IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Civil Action No. 03-10641-NG-RWZ
Civil Action No. 11-10398-NG-RWZ

UNITED STATES OF AMERICA, *et al., ex rel.*

GREGORY W. THORPE and

BLAIR HAMRICK,

Plaintiffs,

v.

SMITH KLINE BEECHAM, INC., and

GLAXOSMITHKLINE PLC d/b/a GLAXOSMITHKLINE,

Defendants.

SEVENTH AMENDED COMPLAINT

FILED UNDER SEAL
PURSUANT TO 31 U.S.C. §§ 3729 *et seq*.

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UNITED STATES OF AMERICA, the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, the DISTRICT OF COLUMBIA AND THE CITIES OF NEW YORK AND CHICAGO, *Ex rel*. GREGORY W. THORPE and BLAIR HAMRICK, and

GREGORY W. THORPE and BLAIR HAMRICK, *individually*,

Plaintiffs,

v.

SMITH KLINE BEECHAM, INC., and

GLAXOSMITHKLINE PLC d/b/a GLAXOSMITHKLINE,

Defendants.

SEVENTH AMENDED COMPLAINT

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PURSUANT TO 31 U.S.C. §§ 3729 *et seq*.

Plaintiffs Greg Thorpe and Blair Hamrick, by their undersigned attorneys, on behalf of the United States of America, the District of Columbia, New York City, the City of Chicago and the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin, state the following as their Seventh Amended Complaint based upon their non-public, indirect and independent knowledge:

I. BACKGROUND

1. This action is brought by relators Greg Thorpe and Blair Hamrick on behalf of the United States of America, the District of Columbia, the City of New York, the City of Chicago, and the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin, to recover compensatory and punitive damages civil penalties pursuant to the False Claims Act, 31 U.S.C. § 3729 *et seq.* and the following state and local false claims acts: the New York City False Claims Act, New York City Administrative Code §7-801-§7-810; and the Municipal Code of Chicago §1-22-010-§1-22-060; the District of Columbia False Claims Act (DC ST § 2-308.03 *et seq.*); the California False Claims Act, (Cal. Gov't Code §§ 12650-12655); the Colorado Medicaid False Claims Act, (Col. Rev. Stat. § 25.5-1-104 *et seq.*); the Connecticut False Claims Act, Chapter 319v, Sec. 17b-301 *et seq.*; the Delaware False Claims and Reporting Act (6 Del. C. § 1201 et seq.); the Florida False Claims Act (Fla. Stat. § 68.081 *et seq*.); the Georgia Medicaid False Claims Act (O.C.G.A. § 49-4-169 *et seq.*); the Hawaii False Claims Act (H.R.S § 661-21 and H.R.S. 46-171 *et seq*.); the Illinois Whistleblower and Reward Protection Act (740 I.L.C.S. § 175/1 *et seq*.); the Indiana False Claims Act (Burns Ind. Code Ann. § 5-11-5.5-1 *et seq.*); the Iowa Medicaid False Claims Act, §685.1 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law (La. R.S. § 46:437.2 *et seq.*); the Maryland False Health Claims Act of 2010 (Subtitle 6, False Claims Against State Health Plans and State Health Programs, § 2-601 *et seq*.); the Massachusetts False Claims Act (M.G.L.A. 12 § 5b *et seq*.); the Michigan Medicaid False Claims Act (M.C.L. § 400.607 *et seq.*); the Minnesota False Claims Act (Minn. Stat. § 15C.01 *et seq.*); the Montana

False Claims Act (Mont. Code Ann. § 17-8-401 *et seq*); the Nevada False Claims Act (N.R.S. § 357.010 *et seq.*); the New Hampshire False Claims Act (R.S.A. § 167:61-a); the New Jersey False Claims Act (New Jersey Statutes 2A:32C-1 *et seq.*); the New Mexico Fraud Against Taxpayers Act (N.M. Stat. Ann. § 44-9-1); the New York False Claims Act (N.Y. C.L.S. St. Fin. § 187 *et seq.*); the North Carolina False Claims Act, N.C. Gen. Stat §§1-605 *et seq.*, the Oklahoma Medicaid False Claims Act (56 Okl. St. § 1005 *et seq.* and 2007 OK. A.L.S. 137); the State False Claims Act of Rhode Island (R.I. Gen. Laws § 91.1-3); the Tennessee Medicaid False Claims Act (T.C.A.§ 71-5-181 *et seq.*); the Texas Medicaid Fraud Prevention Law (Tex. Hum. Res. Code §36.002 *et seq);* the Virginia Fraud Against Taxpayers Act (Va. Code Ann. § 8.01-216.1 *et seq*.); the Wisconsin False Claims for Medical Assistance Act (Updated 05-06 Wis. Stats. § 20.931 *et seq.*). This Seventh Amended Complaint incorporates all exhibits and attachments to the original Complaint and also those exhibits and attachments to the First Amended Complaint previously filed in this action.

2. The aforementioned states, the District of Columbia and the cities of New York and Chicago shall hereinafter be collectively be referred to as the "Plaintiff States." The United States of America and the Plaintiff States shall hereinafter be referred to as the "Government Plaintiffs."

3. This Seventh Amended Complaint incorporates by reference all exhibits and attachments to all complaints previously filed by the Relators in this action. Also incorporated by reference are all documents and other materials referred to in this Seventh Amended Complaint, and all disclosures and supplemental disclosures to the government.

II. PARTIES

4. Relators Greg Thorpe and Blair Hamrick are former employees of GlaxoSmithKline, who have direct and independent information and insider knowledge of illegal and fraudulent marketing practices of Defendant GlaxoSmithKline ("GSK"). GSK's unlawful off-label promotional efforts for the drugs identified herein was intended to, and did, cause the submission of millions of false claims for GSK's drugs that were ineligible for reimbursement to healthcare programs (such as Medicaid and Tricare) funded by the government-plaintiffs. The schemes alleged herein, with respect to each of the drugs, are continuing through the present.

5. The claims were "false" as that term is defined by the false claims acts of the Government Plaintiffs because the prescriptions that gave rise to those claims were for off-label, non-medically accepted uses as defined by the Medicaid Act, or the claims arose from unlawful kickbacks paid by GSK to prescribing physicians.

6. The financial harm to the Government Plaintiffs - and the concomitant financial windfall to GSK - resulting from GSK's nationwide scheme amounts to billions of dollars from 1997 to the present.

7. Formed as the result of a $76 billion merger between Glaxo Wellcome and SmithKline Beecham in 2000, British based GSK is a pharmaceutical, biological and healthcare company with a remarkable claim as one of the largest makers and distributors of pharmaceutical products in the world and is publicly traded on both the New York and London Stock Exchanges.

8. Prior to the merger, SmithKline Beecham Corporation (“SKB”), also a British based pharmaceutical company, was best known in the United States for its antidepressant, Paxil,

but also maintained a highly profitable range of non-medical products ranging from Aquafresh toothpaste to NicoDerm anti-smoking gums and patches.

9. Given the global trend of pharmaceutical companies, the merger with Glaxo Wellcome resulted in an organization with an international marketing presence unlike any other.

10. Consequently, defendants SmithKlineBeecham p.l.c. and GlaxoSmithKline p.l.c. are the corporate entities legally liable for the actions of GlaxoSmithKline and all predecessor corporations during the period of time alleged in this complaint.

11. During the times relevant to this Complaint, GSK employed more than 100,000 people, had more than 80 manufacturing sites in 37 countries, and makes nearly four billion packs of medicines and healthcare products each year. Additionally, GSK boasted the largest sales force (40,000 employees) in the pharmaceutical industry.

12. As recently as 2009, GSK claimed a global market share of approximately 7% and reported sales of over $45 billion, resulting in a net income of more than $8 billion.

13. The global presence of GSK has steadily increased since its merger with SmithKline and, since 2000, the company has acquired Domantis, Praesis Pharmaceuticals and Reliant Pharmaceuticals thereby gaining market share in antibody therapies and cardiovascular medicines.

14. Presently, GSK’s Global Headquarters are located at Glaxo Wellcome House, Berkley Avenue, Greenford, Middlessex, England, and their United States division is headquartered in Triangle Park, North Carolina.

III. JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367 and 31 U.S.C. §3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730.

16. This Court also has jurisdiction because pursuant to 31 U.S.C. §3730(e) of the Federal False Claims Act, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Seventh Amended Complaint or any other Complaint previously filed in this matter. Relators Thorpe and Hamrick, moreover, qualify as "original sources" of the allegations in all complaints filed by Relators, as that term is defined by 31 U.S.C. § 3730(e)(4)(A) and (B), even if a statutorily relevant public disclosure has occurred within the meaning of 31 U.S.C. § 3730(e)(4)(A) and (B).

17. On January 2, 2003, Relators concurrently provided to the Attorney General of the United States and the United States Attorney for the District of Colorado a copy of the original complaint and a disclosure statement summarizing and supported by all known material evidence in accordance with the provisions of 31 U.S.C. §3730(b)(2) and applicable state law. Relators have served the Government Plaintiffs with copies of the amended complaints filed in this action.

18. Relators shall concurrently provide to the Attorney General of the United States and the United States Attorney for the District of Colorado a copy of this Seventh Amended Complaint in accordance with the provisions of 31 U.S.C. §3730(b)(2). Relators shall concurrently provide copies of this Seventh Amended Complaint to the appropriate offices of the Plaintiff States, in accordance with the provisions of their qui tam statutes.

19. This Court has personal jurisdiction and venue over the Defendants pursuant to 28 U.S.C. §§1391(b) and 31 U.S.C. §3732(a) because those sections authorize nationwide service of process and because each Defendant has minimum contacts with the United States. Moreover, Defendants can be found in, reside, and transact business in this District.

20. This Court has supplemental jurisdiction over the State law claims pursuant to 28 U.S.C. §1367(a).

21. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because each Defendant transacts business in this judicial district, and acts proscribed by 31 U.S.C. §3729 have been committed by Defendants in this District. Therefore, venue is proper within the meaning of 28 U.S.C. §1391(b) & (c) and 31 U.S.C. §3732(a).

IV. GENERAL ALLEGATIONS

22. The False Claims Act, 31 U.S.C. § 3729 *et seq.* imposes liability on any person or corporation that knowingly presents or causes to be presented a false or fraudulent claim to the United States government for payment or approval (31 U.S.C. § 3729(a)(1))[1]; any person or corporation that makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the United States government (31 U.S.C. § 3729(a)(2)); and/or, conspires to defraud the Government by getting a false or fraudulent claim allowed or paid (31 U.S.C. § 3729(a)(3)). Proof of specific intent is not required.

23. The FCA provides that any person who violates any of the aforementioned provisions is liable not just for return of all payments falsely made, but also for civil penalties of

[1] 31 U.S.C. §3729(a)(1), (a)(2) and a(3) were amended in 2009 and renumbered. These statutory sections are now styled as 31 U.S.C. 3729(a)(1)(A), (a)(1)(B) and (a)(1)(C), respectively. To the extent that the new language of the amended statute is not retroactive, Plaintiffs assert that any and all false claims submitted after the enactment of the Fraud Enforcement and Recovery Act are deemed to be violations of the FCA, as amended by the Fraud Enforcement and Recovery Act.

up to $11,000 per false claim, and for three times the amount of the damages sustained by the government. The FCA further provides that any person with direct and original knowledge of false claims submitted to the United States by a person or corporation may bring an action on behalf of the United States and may obtain a share of the damages and civil penalties recovered by the United States.

24. The Plaintiff States have enacted *qui tam* laws analogous to the Federal FCA that precisely mirror its language. The same unlawful conduct of Defendants in marketing the drugs alleged herein that gives rise to their liability under the FCA likewise gives rise to their liability under the analogous laws of the Plaintiff States. As such, Defendants are subject to civil monetary fines and penalties under both the FCA and the parallel statutes of the Plaintiff States.

25. From 1997 to the present and continuing, GSK's marketing plan, devised at a senior executive level, has been to "Exploit the Bolus" of government-funded healthcare programs such as Medicaid and Tricare, with the direct and intended effect of causing the submission of false claims to such programs as identified herein.

26. GSK effected this plan in at least the following ways:

- GSK has illegally and fraudulently promoted and marketed the sale of its drugs for off label, non-medically accepted uses, *i.e.* uses not approved by the United States Food and Drug Administration ("FDA") and not supported by the medical compendia identified in the Medicaid Act. As part of this scheme, GSK overtly and aggressively targeted physicians identified by GSK's prescription tracking methods to have the largest volumes of patients enrolled in government-funded healthcare programs such as Medicaid and Tricare.

- GSK has paid illegal remuneration (*i.e.* kickbacks) to physicians and other health care providers with the purpose and intent of inducing those physicians and healthcare providers to prescribe GSK drugs in return in violation of the federal Anti-Kickback law and the analogous anti-kickback laws of the Plaintiff States. GSK's kickback payments include gifting of unrestricted grants to individuals and institutions, paying premium fees to physicians to participate in speaker's bureaus and provide speakers' services, providing remuneration for sham participation on advisory boards and providing substantial sums of money for lavish dinners and entertainment. GSK's kickback scheme, as evidenced by GSK internal records, has proved enormously successful in expanding the off-label market of GSK's drugs, especially the off-label, non-medically accepted use of GSK drugs by beneficiaries of healthcare plans funded by the government-plaintiffs.

27. Top level GSK managers and executives, including but not limited to GSK's Chief Executive Officer J.P. Garnier, current President of Pharmaceutical Operations David Stout, Vice Chairman of Pharmaceuticals (and former President of Pharmaceutical Operations) Robert A. Ingram, Senior Vice President Stan Hull, Regional Director Mike Bennett, and Vice President and Head of Corporate Compliance Arjun Rajaratnam, have been aware of GSK's illegal marketing schemes and have played an active role in supporting and promoting these schemes.

28. GSK executives availed itself of its unparalleled sales force and speaker's bureau, in terms of size, to implement its scheme with maximum financial impact. GSK's Chief Executive Officer J.P. Garnier specifically acknowledged the pervasive power of the company's marketing force by boasting that, because of its unrivaled size of its sales force, GSK had the

ability within a week to reach physicians responsible for 80% of all of the prescriptions written in the United States. President of Pharmaceutical Operations David Stout, in a confidential speech made to members of GSK's sales force in year 2000 (labeled the "Big Orange" tape and reserved expressly for "Glaxo Smith Kline employees only" and "not for external distribution") admitted when discussing the issue of "integrity" that he would not "be proud" to be "a sales representative again" in the "three years, four years" previous to the speech.

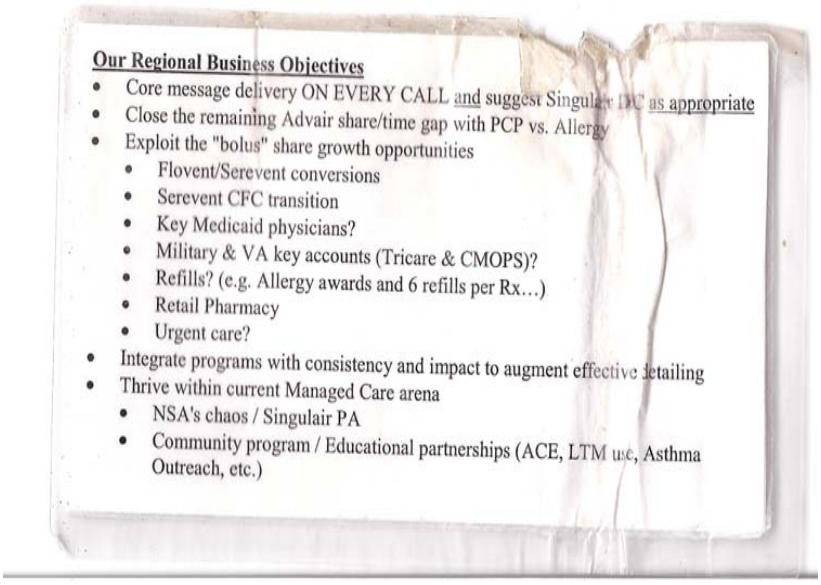
29. To complement its dominant sales force, GSK had equally unrivaled resource of speakers to promote its drugs. GSK's speaker's bureau is comprised of approximately 49,000 physicians, all of whom made their peer-to-peer marketing services available in return for premium compensation. These kickbacks were also a method used by GSK to reward the biggest prescribers of its drug or as a way to incentivize physicians to increase their writing of GSK drug prescriptions.

30. GSK attempted to conceal its scheme by maintaining a 'dual policy' of printing prominent disclaimers on the written materials distributed to its sales force, such as "for internal use only," "not to be used in marketing," and "not to be left in health care offices," while simultaneously encouraging its sales force to ignore such disclaimers and market its prescription products for off-label indications.

31. GSK refers to third party payors for its prescription drugs "targets." Sources such as Medicaid and Tricare/Champus, and "high decile" (high prescribing) physicians, who predominantly treat patients enrolled in Medicaid and Tricare/Champus reimbursement, are labeled "targets" in numerous confidential data sheets, emails and other documents distributed to its marketing force. GSK has consistently pushed its sales representatives to focus their efforts

on gaining the business (i.e. increasing prescriptions) of high prescribing Medicaid and Tricare/Champus physicians.

32. As evidence of GSK's hyper-vigilance paid to success in gaining Medicaid market share, in 2003, GSK Regional Vice President Gregg Far went so far as to distribute to each member of his sales force a laminated wallet-size card to carry at all times to provide a reminder of 3 keys to successfully marketing GSK's drugs. This card directed GSK sales representatives to "**Exploit the Bolus**" to be successful:



33. Relator Hamrick received additional directives specifically to "Exploit the Bolus of Medicaid" in his performance evaluations prepared by his manager.

34. The reimbursement claims GSK caused to be submitted to Medicaid and other government-funded programs for these uses were not eligible for reimbursement, and as such, constituted false claims. Moreover, as alleged herein, GSK caused the submission of these false claims because its marketing efforts specifically targeted physicians who treat large volumes of

beneficiaries of Medicaid, Tricare/CHAMPUS and other government-funded healthcare programs.

A. Drugs Marketed By GSK For Off-Label Use

35. GSK is well aware that physician visits by drug representatives, or 'detailing' as it is known in the industry, has a direct causal impact on the choices physicians make in writing prescriptions. GSK documents establish that the national average for physician visits by GSK sales reps is at least eight per day per representative and the average for retail pharmacies at least three per day per representative. As part of these detailing efforts, GSK requires its sales representatives to be thoroughly conversant with Current Procedural Technology ("CPT") codes relevant to their products and the services of the physicians they visit. Many times the coding and billing advice related to providing services that resulted in off-label use of the GSK drugs: for example, COPD diagnosis codes resulting in an off-label prescription of Advair for COPD.

36. In fact, GSK provides *a toll free number* for physicians and clinics to call for assistance in billing programs such as Medicaid and Tricare/Champus, and particularly for advice concerning appropriate CPT coding.

37. Off-label marketing can be extremely dangerous, given the fact that the FDA has not approved dosage information and there is no "label" which a health care practitioner can turn to for advice. This is especially the case in off-label marketing of GSK's drugs approved for adult use for pediatric patients.

38. Thousands of GSK sales representatives nationwide have detailed physicians for off-label pediatric uses of GSK prescription drugs without the information necessary to establish appropriate dosage. Inadequate dosing information may expose pediatric patients to dangerously high doses or to ineffective treatment.

39. Confidential “return on investment” data maintained by GSK for the time period relevant hereto affirmatively indicates that GSK's aggressive marketing approach, and particularly its programs which compensate health care practitioners and/or provide medical education credits, such as attendance of "peer-to-peer" programs, participation in speaker programs, CME (Continuing Medical Education) programs, participation in preceptorships, serving on therapeutic specialty boards and receiving honorariums, in addition to the numerous social and athletic events, skiing trips, 'spa' meetings and concerts sponsored by GSK during the period in question, have been enormously successful in producing increased sales of its prescription medications.

40. Relators have personal, direct and independent knowledge that GSK implemented nationwide off-label promotional schemes in the following manner for the following drugs:

1. Advair

41. Advair (fluticasone propionate and salmeterol) was first approved by the FDA on August 24, 2000 in dosages of 100/50, 250/50 and 500/50 (these dosages reflect the proportion of fluticasone propionate to salmeterol) for patients 12 and older with moderate to severe asthma whose asthma symptoms were inadequately controlled on a previous course of corticosteroids or whose disease severity warranted daily maintenance therapy with two medications.

42. However, GSK has effusively marketed this prescription drug from the date of its launch as follows for off-label, non-medically accepted uses:

- Since 1999, GSK has promoted all doses of Advair for the treatment of mild intermittent and mild persistent asthma, knowing the drug was not indicated for mild asthma patients;

- Since 1999, GSK has marketed Advair 250/50 for the treatment of Chronic Obstructive Pulmonary Disease ("COPD") even before it received FDA approval in November 2003 for the treatment of COPD *associated with Bronchitis*. Even after the November 2003 approval, GSK marketed Advair 250/50 beyond the limited COPD/bronchitis indication despite the FDA's expanded approval of Advair 250/50 for COPD on April 30, 2008. This off-label marketing for of Advair for COPD continues as of the date of the filing of this Seventh Amended Complaint;
- GSK has marketed Advair 500/50 for the treatment of COPD from 1999 and continuing to the present. Advair 500/50 never received FDA approval for any form of COPD. To the contrary, in August 2007 the FDA *rejected* GSK's supplemental new drug application for Advair 500/50 for COPD;
- Since 1999, GSK has marketed Advair 150/50 and 250/50 for the treatment of pediatric asthma in children under the age of 12 even prior to receiving FDA approval for Advair 100/50 for patients aged 4 through 11 on April 24, 2004; and
- GSK has also marketed Advair in all three doses for uses that were off-label, that were not medically accepted uses, that were not medically necessary, and that were contrary to Black Box warnings subsequently put on the Advair label by the FDA, including active marketing of Advair to African Americans despite knowing and acknowledging that the drug contained a component, salmeterol, that was dangerous to that population sub-group.

2. Amerge

43. Amerge (naratriptan hydrochloride) was initially approved by the FDA on February 10, 1998 for the acute treatment of migraine headache with or without aura in adults

only. Despite the limited FDA approved indications, GSK has aggressively marketed the drug for the following off-label uses:

- For the treatment of tension and sinus headache;
- For the treatment of menstrual migraine, menstrually-related migraine, for prophylaxis for headache and for prophylaxis for menstrual migraine;
- For use in pediatric and adolescent patients for migraine, including the promotion of Amerge as a "long acting" migraine medication;
- For prophylaxis in pediatric and adolescents; and,
- For use during pregnancy as a safer choice comparatively to GSK's second migraine drug Imitrex, on the basis that Amerge is milder and has a favorable side effect profile. However, Amerge has never been specifically approved for use during pregnancy.

3. Flonase

44. Flonase (fluticasone propionate), an aqueous based nasal spray approved by the FDA on October 19, 1994 for the treatment of seasonal and perennial allergic rhinitis. However, GSK has been heavily marketed the drug off label as follows:

- For the treatment of nasal polyps; and,
- As an efficacious "as needed" medication, when in fact, clinical trials show that the drug requires several days of use to build up in the body to achieve maximum effectiveness.

4. Flovent HFA and Flovent Diskus

45. Flovent Diskus (flucticasone propionate/aerosol) was initially approved on September 29, 2000 and Flovent HFA was initially approved on May 14, 2004. Both are currently FDA-approved for the maintenance of asthma as prophylactic therapy in adults and

pediatric patients 4 years of age or older as well as for patients requiring oral corticosteroid therapy for asthma.

46. Despite the FDA's limited indication relating to asthma exclusively, GSK has aggressively marketed Flovent HFA and Flovent Diskus since their launch for the treatment of COPD.

5. Imitrex

47. The FDA gas approved three formulations of Imitrex: Imitrex Injection received its initial approval by the FDA in 1993, followed by approval in tablet form in 1995 and in nasal spray form in 1997. Imitrex Tablets, Nasal Spray and Injection are FDA approved for the acute treatment of migraine attacks with or without aura in adults. Imitrex Injection has a second FDA-approved use, for the acute treatment of cluster headache episodes.

48. Contrary to Imitrex's narrow FDA approvals, GSK has marketed the drug in all of its formulations for the following uses:

- For the treatment of mild headache;
- For the treatment of sinus or tension headache;
- For the treatment of pediatric migraine, with particular focus on the promotion of Imitrex Nasal Spray for this use. GSK promoted the drug for this use by making false assertions to physicians that Imitrex Nasal Spray was on the verge of receiving FDA-approval; and,
- For the treatment of Menstrual Migraine, Prophylaxis and Use During Pregnancy

6. Lamictal

49. In December 1994, Lamictal (active ingredient *lamotrigine*) was FDA approved for use as adjunctive therapy in adults with partial seizures, and as adjunctive therapy in the

generalized seizures of Lennox-Gastaut syndrome in adults and pediatric patients ages two and older.

50. However, despite the narrow indications for which it was approved, GSK heavily marketed Lamictal for the treatment of bipolar disorders both before and during the period it was pending a supplemental new drug application for treatment of bipolar I disorder, which was finally granted by the FDA on June 20, 2003.

51. This new bipolar I indication was far more narrow than the aggressive marketing campaign for the treatment of bipolar disorder which GSK had in place both before and after the June 2003 approval.

52. GSK also marketed Lamictal for a variety of off-label uses for which it never gained subsequent approval, including neuropathic pain, multiple sclerosis, trigeminal neuralgia, peripheral neuropathy, cluster headache and PTSD.

53. Lamictal was subsequently approved in an extended release form known as Lamictal XR. Lamictal XR's approval is limited to adjunctive therapy for primary generalized tonic-clonic seizures and partial onset seizures with or without secondary generalization in patients 13 years of age and older. GSK promoted Lamictal XR for the same off-label uses as Lamictal. In addition, as Lamictal's patent expiration date came closer, GSK sales representatives were trained to promote switches to Lamitcal XR, including those prescriptions known to be written off-label.

54. GSK's off-label promotion of Lamictal and Lamictal XR recklessly disregarded the drug's serious side effect of rash, which can result in hospitalization or even death.

7. Paxil

55. Paxil (paroxetine hydrochloride) was initially approved by the FDA on December 29, 1992 for the treatment of Major Depressive Disorder in adults. Thereafter, the FDA approved the drug for other uses, however neither Paxil, nor its extended release formulation known as Paxil CR, has been approved for any use whatsoever in patients under the age of 18.

56. Nevertheless, GSK has aggressively promoted Paxil and Paxil CR as a safe and effective treatment for a litany of mental issues for children, including, depression, anxiety, ADHD, shyness, and bi polar disorder, among others.

57. GSK's off-label marketing for pediatric use was particularly egregious because GSK knew no later than November 1998 that Paxil was *ineffective* in this age group and, even worse, that depressed pediatric users of Paxil were up to three times more likely to commit suicide or engage in other self-harming conduct. GSK not only knew these seminal facts, but withheld its own clinical study data that proved them to be true from the medical community and the public to protect pediatric Paxil sales.

58. However, the bulk of Paxil and Paxil CR sales stemmed from GSK's unlawful promotion for off-label uses in adult patients for such diverse disorders as premature ejaculation and general social phobias, anxiety, ADHD, shyness, and bipolar disorder. As part of this scheme, GSK concealed that Paxil is highly addictive.

59. Finally, GSK aggressively promoted Paxil as safe and effective for use during pregnancy. This marketing scheme rivals the contemptibility of its pediatric scheme. GSK characterized Paxil as having treatment benefits that outweighed the risks, when in fact GSK knew the opposite to be true. GSK knew that the drug substantially increased the risk of severe congenital birth defects, particularly holes in the heart of the fetus. The drug is now also known

to cause Persistent Pulmonary Hypertension of the Newborn. When information about Paxil's link to birth defects finally became public in December 2005, the FDA reclassified the drug as Category D. Category D classification is reserved for drugs with a proven link to birth defects when used during pregnancy.

60. Paxil is the only SSRI with a Category D designation. GSK's concealment of evidence of birth defects deprived physicians and expecting mothers of the ability to make informed choices about the risks of its use during pregnancy. Had GSK disclosed the truth, undoubtedly the use of Paxil during pregnancy would have been severely curbed, which is exactly what GSK endeavored to avoid. This is particularly true of off-label use of Paxil, where safer alternatives would have been available.

8. Valtrex

61. On June 23, 1995, the FDA approved Valtrex caplets (valacyclovir hydrochloride) for the treatment of Herpes Zoster, commonly known as “shingles” in adults.

62. Shortly thereafter, on December 15, 1995, the FDA approved Valtrex caplets for the treatment of Recurrent Genital Herpes in adults.

63. On September 9, 2002, Valtrex received FDA approval, and its first pediatric indication, for the treatment of Herpes Labialis (cold sores) in adults and adolescent patients 12 years and older.

64. On April 1, 2003, the FDA approved Valtrex for use in the suppression of Recurrent Genital Herpes.

65. Following the suppression indication, on August 29, 2003, Valtrex was approved for these uses in combination with safe sex practices to reduce risk of transmission of herpes in heterosexual couples.

66. Finally, on September 2, 2008, the FDA approved Valtrex for the treatment of chicken pox in children between 2 years and 18 years old.

67. Although it eventually received the aforementioned FDA indications, GSK marketed Valtrex for uses well in advance of approvals and, in some instances, pushed the drug for prophylactic use in the 2nd and 3rd trimesters of pregnancy to prevent transmission to the fetus, and the treatment of multiple sclerosis.

9. Wellbutrin

68. Initially approved by the FDA on December 30, 1985, Wellbutrin (bupropion hydrochloride), was indicated for the treatment of Major Depressive Disorder ("MDD").

69. On October 4, 1996, the FDA approved Wellbutrin SR (sustained release) tablets for the treatment of MDD in adults.

70. In 2003, the FDA approved the use of Wellbutrin XL (extended release) for the treatment of MDD in adults.

71. Wellbutrin, Wellbutrin SR and Wellbutrin XL have never received FDA approval for pediatric use.

72. Despite their narrow MDD indications , GSK has aggressively promoted this drug, in all of its formulations, in pediatric psychological disorders, weight loss, ADHD (Attention Deficit Hyperactivity Disorder) in adults and children, for anxiety co-morbid to depression, for co-administration with SSRI's (selective serotonin re-uptake inhibitors), sexual dysfunction, bipolar disease and addictions, including smoking cessation and for treatment of depression in pregnant women, and a litany of other off-label uses detailed herein.

10. Zofran

73. On January 4, 1991, Zofran (ondansetron hydrochloride) was approved by the FDA for the prevention of nausea and vomiting induced by chemotherapy and radiation therapy as well as the prevention of post-operative nausea and vomiting.

74. Since its initial approval as an injectable, Zofran has received subsequent approvals on January 24, 1997 for an oral solution and on January 27, 1999 for an orally disintegrating tablet.

75. On March 25, 2005, Zofran received FDA approval for use in children as young as one (1) month of age to prevent nausea and vomiting associated with general anesthesia, and for use in children as young as six (6) months to prevent nausea and vomiting associated with chemotherapy.

76. Despite the limited indication, GSK attempted to expand dramatically the off-label use of Zofran and has marketed the medication for the treatment of morning sickness in pregnant women, as well as nausea and vomiting associated with influenza and gastrointestinal distress.

11. Zyban

77. Zyban (bupropion), was originally approved by the FDA on May 14, 1997 as a smoking cessation drug.

78. Although it contains the same ingredient as Wellbutrin, because federal law prohibits Medicaid from being compensating drugs identified and approved specifically for smoking cessation, GSK elected to promote Zyban off-label for use in pregnancy and in the treatment of non-nicotine addictions.

V. GSK'S RETALIATORY DISCHARGES OF RELATORS THORPE AND HAMRICK

A. Relator Thorpe's Employment with GSK

79. Relator Thorpe, a career pharmaceutical sales representative, earned his way through several promotions to a senior executive sales position with GSK after having been employed continuously with GSK and its predecessor corporations from 1978 to 2002. Thorpe was one of the first 100 sales employees hired for Glaxo Inc. *See Exhibit "A" attached hereto at pages 7AC 0000001-0000003.*[2]

80. Thorpe managed the Cerenex Division in Colorado Springs, Colorado and had responsibility for detailing and running "programs" for primary care physicians, neurologists and psychiatrists. Thorpe's sales presentations included in-service programs, speaker programs, and direct product presentations to physicians, pharmacists, hospitals, managed care branches, and other ancillary medical providers. His product lines included Imitrex, Amerge, Wellbutrin SR, Zyban, Lamictal and Valtrex.

81. Thorpe was a top performer for GSK, receiving many company awards and company recognition. He had sales experience in a wide range of therapeutic categories, including anti-infectives, respiratory medications, anti-hypertensives, anti-inflammatories, ulcer medications, anti-emetics, antifungals and steroidal products.

82. During his time with GSK, Thorpe was three times awarded with membership in the "President's Club," twelve times he was Sales Representative of the Semester/Quarter, and he served as a District Sales Trainer. Until 2001, when he began to voice complaints about GSK's illegal marketing practices, Thorpe received outstanding performance evaluations.

[2] All document references herein are attached as Exhibit "A".

83. Thorpe's employment difficulties with GSK started when he began to complain about illegal marketing practices in 2001, and when he resisted efforts on the part of his superiors and co-workers to set up what he believed to be illegal programs. At this time, Thorpe complained to District Manager Pat Keith, Regional Vice President Mike Bennett, as well as Sales Representatives Annie Cutter and Ronald Crews about illegal marketing practices he witnessed and in which he was asked to participate.

84. Prior to September 17, 2001, when Thorpe was given a "field coaching contact report" from his immediate supervisor stating that he was not a "team player," Thorpe had refused to participate in a lecture program set up by GSK in which Dr. Fred Michel, a pediatric psychiatrist, was paid by GSK to lecture on off label uses of Wellbutrin SR, including the use of for the treatment of ADHD in children, before a group of approximately 60 physicians.

85. Thorpe had also refused to participate in setting up and attending a lecture and dinner program on May 23, 2001 in Colorado Springs, Colorado by Dr. Paul Wender, whom GSK flew in to lecture local physicians on the efficacy of Wellbutrin in the treatment of adult and pediatric ADHD. Thorpe additionally refused to participate in setting up special "events," such as a spa weekend at a local luxury hotel for a number of physicians that was initiated by GSK Sales Representative Cutter, as well as an extravagant ski trip GSK sponsored for physicians. *7AC 0000004-0000005.*

86. On October 1, 2001, in a meeting attended by Thorpe, District Manager Keith, and Regional Vice President Bennett, Thorpe was issued a formal "verbal warning," which actually was reduced to writing. Issuance of this written "verbal" warning is used by GSK as the first step in the progressive discipline process, a process which can include termination from employment. *7AC 0000006-0000007.*

87. In that meeting Thorpe pointed out that GSK Sales Representative Crews had insisted on setting up events for doctors which were entirely for the purpose of providing free food, drink and entertainment in order to secure additional business, and which provided no medical educational benefit to the attendees.

88. Thorpe also brought up in this meeting specific GSK programs in which he had refused to participate, including GSK's payment to the Chief Psychiatrist for the Pikes Peak Community Health Center for addressing a group of physicians on the benefits of Wellbutrin SR in the treatment of ADD in adults and ADHD in children. GSK had neither an indication nor a pending NDA for either of these uses. Pikes Peak Community Health Center at the time had a patient population which was overwhelmingly enrolled in the Medicaid program.

89. At this time Thorpe also indicated that he objected to having had to forward a GSK check to a nurse practitioner for her to deliver a lecture in Keystone, Colorado to a nationwide group of health care practitioners on the benefits of Amerge in the treatment of pediatric migraine, an off-label use for which GSK has never submitted an NDA.

90. Lastly, Thorpe informed GSK management at this meeting that he had been asked to recruit a local physician, Dr. Marciniak, to lecture other physicians about the off-label prescription of Lamictal for the treatment of bi-polar disorder. To support the allegation, Thorpe showed both Messrs. Keith and Bennett contact reports which demonstrated off-label marketing of Wellbutrin for ADHD in children and Lamictal for bipolar disorder to physicians in the Colorado region.

91. "Contact reports" are electronic forms GSK required its sales representatives to fill out following a physician sales call. Contact reports capture key data about a sales call,

including the physician's name, the date, a summary of what was discussed during the call and identified any samples left behind

92. In a letter dated October 16, 2001, Thorpe's counsel at the time requested that GSK reconsider the "verbal" warning the company had issued to his client, due to the fact the "lack of teamwork" allegation asserted against Thorpe was based on Thorpe's refusal to engage in illegal marketing activity, as well as his reports and complaints about such activity.

93. On December 11, 2001, Thorpe sent an e-mail to Arjun Rajaratnam, a GSK Senior Vice President and Head of GSK's Global Corporate Compliance. Attached to the e-mail was a copy of GSK's "Pharma Compliance: Your Partner on the High Road" memo. This memorandum announced to all GSK employees an upcoming "fact sheet" concerning new Pharma Compliance guidelines. In the e-mail to Rajaratnam, Thorpe complained that he had been retaliated against for turning in his co-workers for illegal off-label promotion and kickback activities. This was conduct which had been approved by managers Keith and Bennett, as well as the company's Speakers Bureau. *7AC 0000013-0000014.*

94. On January 2, 2002, Thorpe finally received a response to his e-mail. In that response, Rajaratnam stated that he would look into the allegations. *Id.*

95. On January 7, 2002, GSK Regional Compliance Officer Teri Schaffer traveled to Colorado Springs to interview Thorpe. At that time, Schaffer reported directly to Rajaratnam. During this interview, Thorpe handed Schaffer a typewritten "To Whom It May Concern" document he had prepared (the "January 2002 Document"). This document detailed the illegal marketing activities about which he had previously complained, and also stated Thorpe's belief that the "verbal" warning issued to him after more than 23 years of service to the company was retaliatory. *7AC 0000015-0000029.*

96. In the January 2002 Document, Thorpe stated that GSK had ignored his complaints and requests for information he had sent to the company since March 2001. Thorpe detailed the payment to Dr. Wender to speak off-label on Wellbutrin for ADHD, the payment of a nurse practitioner to lecture 200 persons from across the country on the use of Amerge for pediatric migraine, the ski bus trips to Breckenridge, Colorado for physicians paid for by GSK, the Colorado Avalanche tickets provided to physicians. In the January 2002 Document Thorpe characterized this conduct as "buying business through bribery." *Id.*

97. In this same document Thorpe also objected to the fact that GSK had paid several thousand dollars to a General Practitioner Brendan Montano, M.D., who had been elevated to a national speaker and "thought leader" status by GSK, to lecture a group of Colorado physicians on the use of Wellbutrin for weight loss, an indication never approved by the FDA. *Id.*

98. On January 30, 2002, Schaffer and Corporate Compliance Officer Barry Eckles interviewed the individuals Thorpe had identified as having been involved in illegal conduct. These identified persons included Bennett, Crews, Cutter, Hosler and Keith.

99. On February 11, 2002, Carrie Rubright, Human Resources Director of GSK's Western Region, along with another representative of the GSK Legal Department, spoke at a regularly-scheduled regional meeting of GSK sales representatives. At this meeting, Rubright reiterated previous GSK guidelines concerning entertainment of and gift giving to physicians. There was no discussion about paying physicians to lecture other physicians on off-label uses.

100. At this February 11, 2002 meeting, Rubright told Thorpe that GSK compliance personnel were reviewing his complaints and that he would be contacted on February 22, 2002. She also informed him there had recently been held a meeting of several of the highest-ranking officers and managers of GSK, and that at this meeting Thorpe's January 2002 Document, as

well as other of his related documents, had been extensively discussed. While Rubright indicated to Thorpe that other executives had attended this meeting, the only individuals she identified were Robert Ingram, then Chief Operating Officer of GSK, and David Stout, President of U.S. Pharmaceuticals.

101. On February 22, 2002, not having heard from anyone regarding the status of his complaints, Thorpe began calling and e-mailing the GSK Human Resources Department. Thorpe was eventually able to reach Director Schaffer. Schaffer at that time informed Thorpe that he would be placed on administrative leave until the review of his complaints and request for an internal investigation were completed.

102. On March 11, 2002, Thorpe had a conference call with Rajaratnam and Rubright. In that call, Rajaratnam informed Thorpe that his complaints had been fully investigated, but that his "verbal" warning for not being a team player would remain in his personnel file. Additionally, although Thorpe had made clear in the January 2002 Document he believed his supervisor (Keith) had been involved in illegal marketing, Rajaratnam refused to assign Thorpe to another supervisor and insisted that he return to work under Keith.

103. On March 18, 2002, a conference call was arranged among GSK Corporate Counsel for Human Resources Belinda Reed Shannon, counsel for GSK, Rajaratnam, Rubright and Thorpe. During this telephonic conversation, GSK officials and counsel offered Thorpe the following proposal to resolve their dispute: in exchange for Thorpe executing a waiver and release of all legal claims against GSK, Thorpe would receive from GSK (a) $11,000 towards the purchase of his company car; (b) $80,000 to cover Thorpe's relocation costs to Arkansas; and (c) both his Cash Balance Plan Enhancement *and* the monetary value of his Enhanced Separation Program (the "Settlement Agreement"). *7AC 0000008-0000010.*

104. In accordance with GSK policy at the time, Thorpe's Enhanced Separation Program in turn consisted of the payment of unused vacation, two months' compensation, family medical insurance and family dental insurance.

105. Thorpe subsequently concluded he could no longer work under the supervision of Keith without involving himself in illegal and potentially criminal activity in the marketing of GSK prescription drugs. After some additional negotiation, Thorpe accepted the Settlement Agreement.

106. On August 31, 2002, Thorpe's employment with GSK was terminated. *7AC 0000034-0000038.*

107. GSK substantially and materially breached the Settlement Agreement in at least the following ways: (a) GSK failed to make any payment to Thorpe towards his purchase of his company car; (b) GSK paid Thorpe only $44,000 of the $80,000 it had contracted to pay to Thorpe for his relocation expenses; (c) GSK failed completely to pay Thorpe his Cash Balance Plan Enhancement; and (d) GSK failed to pay for dental insurance to cover the Thorpe family.

108. On November 15, 2002, Thorpe wrote to Shannon, with copies of the letter to Stout and Ingram. Among other things, in said letter Thorpe took the position that GSK had breached the Settlement Agreement. *7AC 0000039-0000040.*

109. Upon information and belief, following Thorpe's termination from GSK, GSK had a direct and material role in causing Thorpe to become unemployable within the pharmaceutical industry. Despite being a seasoned, highly proficient, knowledgeable marketing representative, Thorpe applied for positions with the following pharmaceutical companies, but was been rejected by each and every one of them:

- Wyeth Labs on 9/16/03, 9/18/03, and 9/19/03;

- Merck, Inc. on 9/20/03 (2 applications), 1/15/04, 1/16/04, 1/19/04, 1/23/04, 1/27/04, 2/05/04 (4 applications for the respiratory division), 2/06/04, 2/11/04, 3/09/04, and 6/2003-1/2005 (6 separate applications);
- Boheringer- Ingelheim on 10/18/03;
- Hoechst Marion Roussel on 12/19/03;
- Aventis on 12/19/03 (2 applications);
- Roche on 12/22/03;
- Novartis on 12/22/03;
- Sandoz on 12/24/03;
- Organon USA on 12/24/03;
- Johnson and Johnson on 1/6/04;
- Pfizer, Inc. on 11/04/03, 11/05/03, 11/06/03, 01/08/04, and 01/24/04;
- Kos Pharma on 10/02/03;
- Forest Labs on 10/10/03, 11/05/03, and 02/14/04;
- Eli Lilly on 10/18/03 and 02/16/04; Abbott Labs on 10/31/03;
- Astra Zeneca on 11/11/03, 01/23/04, and 04/12/04;
- Baxter Labs on 11/20/03 (3 applications);
- Schering Plough on 11/26/03, 11/27/03, 12/04/03, and 01/29/04;
- Genentech on 12/04/03 (3 applications);
- Bayer on 12/04/03;
- Proctor and Gamble on 12/11/03 (3 applications);
- Biovail Corp. on 12/11/03 (2 applications);
- Elan on 2/20/04 (3 applications);
- Adalor in 12/2004.

B. Relator Hamrick's Employment with GSK

110. Blair Hamrick began his employment with GSK as a Professional Sales Representative in 1997, having worked for other pharmaceutical companies for several years. During his time with GSK he became a top performer, with specialized training in the following practice areas: General Practice, Family Practice, Pediatrics, Internal Medicine, Infectious Disease, OB/GYN, Neurology, Emergency Medicine, Respiratory and Psychiatry. *7AC 0000041-0000043.*

111. In 1999 Hamrick was promoted to the position of Specialty Representative, and in that capacity helped to launch Lotronex, a product which was pulled from the market shortly after its approval by the FDA. For his productivity in 1999, in 2000 Hamrick was awarded

GSK's "President's Trophy," in 2000. This prestigious award is given only to the top 10% of GSK's sales associates. In 2001, Hamrick was also employed in the respiratory area to help with the promotion of GSK's blockbuster drug Advair.

112. Hamrick's previously stellar career with GSK began its downward turn in April of 2001 when he reported thefts of Colorado Avalanche tickets by GSK employees; these tickets were intended to be gifts for physicians. *7AC 0000044-0000046.* Also in 2001, Hamrick discussed the Paul Wender Programs described *supra* with his supervisor, Pat Keith. Hamrick informed Keith he would not participate in the Wender Programs because he believed them to involved illegal activities. Shortly thereafter Hamrick was demoted to a regular sales representative position.

113. On January 30, 2002, Hamrick was interviewed by Schaffer and Eckles in the course of their investigation of Thorpe's complaints about unlawful conduct undertaken by or with the knowledge of GSKs' management. Hamrick informed Schaffer and Eckles that he had refused to participate in marketing schemes such as the Paul Wender dinner program/promotion for Wellbutrin in ADHD in children.

114. Also at the January 30, 2002 meeting, both orally and by written statement, Hamrick confirmed the validity of Thorpe's allegations concerning payment to doctors and other speakers to influence physicians to prescribe GSK products drugs for off-label uses. Hamrick specifically mentioned GSK's aggressive marketing of Imitrex for pediatric use, an off-label use for which GSK has never sought FDA approval. Finally, Hamrick also provided a written statement regarding his knowledge of the theft of the Colorado Avalanche tickets.

115. Since the Spring of 2001, GSK began treating Hamrick as a "problem" employee. This negative treatment of Hamrick began to significantly worsen significantly, however, after

the January 30, 2002 meeting. By the Summer of 2002, it had become clear that GSK wanted Hamrick out of the company.

116. In February of 2003, one month after this action was filed, both Relators began to actively cooperate with investigators and attorneys from the United States Department of Justice, the Food and Drug Administration, the Federal Bureau of Investigation, and the Department of Defense in the their investigation of GSK's illegal marketing practices. At about this time, Hamrick requested he be permitted to inspect the contents of his GSK personnel file. GSK management informed Hamrick his request would be granted only if he agreed to be questioned by GSK counsel alone and without any counsel or representative present. Hamrick declined to be questioned in this manner.

117. On September 30, 2003, Hamrick received a harsh letter from Rajaratnam threatening an "incident report" for a very minor discrepancy in electronic sample records. *7AC 0000048.* Because of the emotional strain he began to feel caused by being treated as an outcast at his place of employment, Hamrick took a medical leave of absence from October 24, 2003 until January 27, 2004, when he was cleared to return to work by his personal physician. *7AC 0000049-0000050.*

118. In late 2003 or early 2004, Hamrick wrote a letter to GSK management, asking that action be taken against colleagues and supervisors who were destroying incriminating company documents in violation of the document hold which had been placed on these papers by the GSK Legal Department. This document hold was in place as a result of the ongoing investigation by several federal law enforcement agencies into GSK activities alleged in this action to be in violation of the Act.

119. Hamrick never received any response to this letter complaint, nor did he ever witness any action taken by GSK to discipline those employees who had violated the document hold, or to stop the document destruction from continuing unimpeded.

120. In February of 2004, GSK Human Resources Manager Claudia Pattison came to Denver to discuss the issue of Hamrick's son being taken out of class in November of 2003 by teacher Miles Copeland, wife of Executive Sales Representative Peter Copeland. In that incident, Hamrick's then eight-year-old son was taken out of class by Miles Copeland and asked inappropriate questions about his father's mental stability. Hamrick was understandably upset about this incident, and told Pattison as much during this meeting. *7AC 000051-0000053.*

121. During this same February 2004 meeting, Hamrick also communicated to Pattison his objection to and disapproval of the following activities undertaken with the knowledge and approval of GSK's management: (a) payment of $25,000 to Colorado Asthma and Allergy for their "Breath Better Bus," an "honorarium" Hamrick believed was paid to influence physicians' prescribing habits; (b) payment in the range of approximately $25,000 to $35,0000 to Dr. Joseph Broughton, an advisory member of GSK's Chronic Obstructive Pulmonary Disease Board; (c) a directive from Hamrick's immediate supervisor, Ned Schneidewind, to sales representatives that they promote the sale of Advair for off-label uses; and (d) the directive to sales representatives from Market Development Manager John Foy, during a Regional Meeting held in Las Vegas, Nev., in September of 2003, to destroy or delete all PowerPoint presentations used by physicians retained by GSK to promote unlawful uses of its drugs, even though GSK's Legal Department had recently placed a document hold on all such materials.

122. At a joint regional meeting of all sales representatives in Dallas, Texas, in March of 2004, Hamrick was called out of a national meeting by Pattison, and taken to a separate room

to be interrogated by security official Rick Demberger. The subject of this interrogation was again the incident at school involving Hamrick's son. Hamrick expressed to Demberger his disapproval of Miles Copeland's actions and of GSK's handling of the situation, but at no time did Hamrick ever make any threatening comments. *7AC 0000054.*

123. On March 17, 2004, Hamrick was taken by security personnel and, in plain sight of front the many of other GSK employees attending the joint regional meeting, he was asked to leave the building in which the meeting was taking place and told to return home early to Colorado. He was then placed on "administrative leave." *Id.* On March 29, 2004, GSK formally notified Hamrick that the reason for the administrative leave was his allegedly emotional reaction to the investigator's questions in Dallas concerning his son being taken out of class.

124. On a nearly daily basis while he was on administrative leave, Hamrick was contacted by GSK personnel and asked: "Why don't you just resign?" At times during these calls he was also asked: "What will it take for you to leave?"

125. On April 2, 2004, Hamrick received a letter from GSK's Human Resources Department, signed by a "Nurse Case Manager" named Marilyn Coston, requesting that Hamrick report to a psychiatrist for a "fitness for duty" evaluation. GSK was insistent on the fitness for duty psychiatric evaluation even after it received an April 16, 2004 letter from a physician for Hamrick stating that he was fit to return to work with GSK. *7AC 0000055.*

126. Concurrently with the request that he submit to a fitness for duty evaluation, Hamrick was contacted by security personnel from GSK, Rick Demberger, who suggested that he consider resigning from GSK and accepting a "severance package." Demberger wanted Hamrick to give him a letter outlining what Hamrick would require to sign a waiver and release of all claims against GSK.

127. At this point, GSK had made it clear to it was clear to Hamrick that GSK he would not be brought bringing him back to active duty. Therefore, on April 19, 2004, Hamrick notified Demberger he would accept a severance package, but he would not agree to sign any form of waiver or release. *7AC 0000056-0000057.*

128. Human Resources Manager Pattison finally responded to Hamrick in a letter dated June 2, 2004, insisting that Hamrick sign a release of claims in exchange for a severance package. *7AC 0000058-0000062.* Hamrick wrote to Pattison, stating he would not sign a release of claims, but would be willing to continue working for GSK. Hamrick stated he preferred a transfer to the Tampa, Florida region where he had family, but if that were not possible, then returning to his previous position in Denver, CO would be acceptable to him. *7AC 0000063-0000064.*

129. Also in June of 2004, officials from GSK contacted Hamrick through his counsel and requested they meet with Hamrick at Denver International Airport to discuss his employment issues as well as his allegations of marketing misconduct. GSK personnel insisted, however, that Hamrick speak to Human Resources personnel without his counsel being present, a condition Hamrick, through counsel, rejected.

130. As a result, Hamrick remained on administrative leave during this period of time. He continued, however, to inform GSK management that he would like to maintain his job if he could be relocated.

131. On September 1, 2004, Hamrick received correspondence from Geoffrey Hobart, counsel for GSK. Hobart was representing GSK in the course of Justice Department's investigation of the company's illegal marketing activities. Hobart insisted that Hamrick's earlier refusal to speak with GSK officials about his allegations of illegal conduct was a violation

of GSK's internal policies. *7AC 0000065-0000066.* On September 3, 2004, Hamrick's counsel replied to this contention by offering to have Hamrick meet with GSK personnel and/or attorneys if he received written confirmation from GSK that he was still an employee of the company, and that a decision to terminate his employment had not already been made. *7AC 0000067-0000068.*

132. On September 24, 2004, GSK sent correspondence to Hamrick, making it clear the company would not provide the assurances he had requested. It is for this reason, in addition to Hamrick's concern about the possibility of violating this Court's sealing order, Hamrick declined to be interviewed by GSK's attorneys.

133. In a letter dated October 13, 2004, GSK Corporate Counsel Shannon wrote to Hamrick's counsel, informing him that Hamrick's employment with the company had been terminated. In the letter, Shannon insisted the decision to terminate Hamrick's employment had not already been made. *7AC 0000069-0000070.*

134. In this letter Shannon set forth the three reasons upon which GSK had allegedly relied when it made its decision to discharge. These reasons were: (a) Hamrick's alleged reaction to the questioning about the school incident involving his son in March of 2004; (b) Hamrick's receipt of a traffic violation while driving his own vehicle off-duty in October of 2003; and, (c) Hamrick's alleged refusal to cooperate with GSK's internal investigation. *Id.*

135. All three of these reasons are pretextual. With respect to reasons (a) and (b), they both were events which had occurred long before GSK discovered that Hamrick was cooperating with the federal law enforcement agencies' investigations into GSK's conduct which was in violation of the FCA, yet GSK did not make the termination decision until after they learned of Hamrick's involvement in the investigations. With regard to reason (c), it is simply false, as Hamrick would have cooperated with the company's internal investigation had its counsel and

management not imposed unacceptable pre-conditions on Hamrick's discussions with its representatives. Finally, all of these reasons are false, inconsistent and otherwise not worthy of belief.

VI. APPLICABLE LAW

A. Law Relating to Distribution of Prescription Medications for Uses Not Approved by the Food and Drug Administration.

136. Under the Food, Drug, and Cosmetics Act (FDCA), pharmaceutical drugs cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. §§ 301-397. An intended use refers to the precise medical condition for which the drug has been approved, the dosage and administration regimen, and the patient population for which the drug may be used. To obtain approval a manufacturer must submit a New Drug Application (NDA) to the Food and Drug Administration for any intended use not already approved. The NDA, in order to be approved, must detail the intended therapeutic use and provide the clinical trial data the manufacturer is relying upon for approval.

137. The clinical trials necessary to support approval of a new indication are expensive and time consuming. By regulation, the NDA must include studies relating to the proposed indication particularly referencing possible adverse effects, must define the pharmacologic properties of the drug, must have a description and analysis of each controlled clinical study pertinent to the intended use of the drug and must have an "integrated summary of the data demonstrating substantial evidence of effectiveness for the claimed indications." 21 C.F.R. §314.50(d). The statute and supporting regulatory scheme are intended to protect the general population from taking drugs not appropriate to their medical condition, receiving inappropriate

dosage amounts, mixing different medications and other practices which in some cases can be harmful or even fatal to patients.

138. The FDCA provides that a drug is misbranded unless the labeling contains adequate directions for use. 21 U.S.C. §352(f)(1). The phrase "adequate directions for use" is further defined in the regulations to mean "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. §201.5. These directions must include *all intended uses and must include dosages and frequency of administration.* 21 C.F.R. §201.5(a), (b) and (c). If there are "intended uses" not included in the drug's labeling, the drug is misbranded. The words "intended uses" "refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the articles, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." 21 C.F.R. §201.128. If a drug is marketed by a company's representatives for a therapeutic use not already approved by the FDA, the drug is misbranded and is being sold illegally. 21 U.S.C. §352(f)(1). Additionally, federal law requires that services and items reimbursed by Medicaid and Medicare be provided "only when, and to the extent, medically necessary" and that they be of "a quality which meets professionally recognized standards of health care." State Medicaid programs generally define "medical necessity," and most program policies indicate that medically necessary treatment need be consistent with scientifically based guidelines of national organizations and/or governmental agencies.

139. Despite the FDCA's prohibition against misbranding drugs, no law prohibits physicians and other licensed health care providers from prescribing a drug for uses other than those approved by the FDA. Therapeutic uses not approved by the FDA are commonly known as non-indicated or "off label" uses. The FDCA places limits on the dissemination of published materials and other data concerning "off label" uses by pharmaceutical companies to health care practitioners.

140. The FDCA and the regulatory scheme supporting the FDCA permit drug companies to disseminate published materials, including scholarly articles published in medical journals, under certain limited circumstances. First, the dissemination of those materials must relate to a therapeutic use for which an NDA or supplemental NDA has been filed with the FDA. 21 USCA § 360aaa. Additionally, the document must include: a prominently displayed statement that discloses that the information concerns a use of a drug or device that has not been approved or cleared by the Food and Drug Administration; if applicable, that the information is being disseminated at the expense of the manufacturer; if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer; the official labeling for the drug or device and all updates with respect to the labeling; if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated; and the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or device for which such information is being disseminated. 21 U.S.C.A. § 360aaa.

141. The regulations have additional requirements for the dissemination of medical literature on off-label uses, including the requirement that the publication(s) distributed generally

"[N]ot be false or misleading. FDA may consider information disseminated under this part to be false or misleading if, among other things, the information includes *only favorable publications* when *unfavorable publications exist...*" (21 CFR § 99.101(a)(4)), or the information poses "a significant risk to the public health." 21 U.S.C. §360aaa-1(a)(2), 21 CFR § 99.101(a)(3).

142. The technical requirements for the dissemination of medical literature and other documents supporting non-approved uses do not apply to any documents disseminated in response to an unsolicited request from a health care provider.21USCA § 557(a); 21CFR § 99.1(2)(b). This law provides a "safe harbor" to drug companies that disseminate information about off-label uses to health care practitioners if they can prove that the documents were distributed at the request of the practitioner. It also enables an unscrupulous manufacturer to distribute medical literature and other materials under the pretense that the information was unsolicited, thus avoiding the onerous technical requirements of the FDCA and its regulations, including the requirement of providing in every instance a balanced presentation of favorable and unfavorable supporting material.

B. Regulations Excluding Reimbursement for Off-label Prescription Drug Uses by Government-Funded Health Care Programs.

143. While physicians are free to prescribe drugs off-label, pharmaceutical companies are prohibited by law from promoting drugs for uses and dosages not approved by the FDA. In addition, payment for off-label uses of prescription drugs by government-funded healthcare programs is highly regulated and restricted pursuant to the laws set forth below.

144. When drug manufacturers promote their drugs off-label, this causes the submission of false claims to *inter alia*, government funded health care programs.

1. The Social Security Act and Medicaid

145. Title XIX of the Social Security Act enacted a program that provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the federal and state governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children. Among the health benefits funded primarily by Medicaid, up until January 1, 2006, was funding for the prescription drug needs of the Program's beneficiaries.

146. A State must have a plan for medical assistance that has been approved by the Centers for Medicare and Medicaid Services (CMS), which administers the program on behalf of the Secretary of Health and Human Services to participate in the Medicaid program. The state plan must specify, among other things, the specific kinds of medical care and services that will be covered. 42 U.S.C. § 1396a(a)(10) and (17). If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, *i.e.*, reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. *Id.* at §§ 1396b(a)(I), 1396d(b).

147. States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances. While the Medicaid Act requires States to provide certain basic services, the Act permits, but does not require, States to cover prescription drugs, although most States choose to do so. 42 U.S.C. § 1396d(a)(12).

148. In 1990, Congress enacted the Medicaid Drug Rebate Statute, codified at 42 U.S.C. §1396r-8, to "establish a rebate mechanism in order to give Medicaid the benefit of the

best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). That statute prohibits federal financial participation for covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8. See 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(I). Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan.

149. However, there are several provisions of the Medicaid Act that permit a State to exclude or restrict coverage. 42 U.S.C. § 1396a(a)(54); H.R. Rep. No. 881 at 97,98. A State may restrict from coverage or exclude altogether certain drugs or classes of drugs, or certain medical uses, such as drugs used for, among other things, cosmetic purposes. 42 U.S.C. § 1396r-8(d)(l)(B)(ii). Relevant hereto is the provision which permits a State to exclude or restrict coverage of a drug where "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(l)(B)(i).

150. Under the statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 355 & 357. It does not include "a drug or biological use for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3).

151. The statute defines "medically accepted indication" as: any use for a covered outpatient drug which is approved under the [FDCA], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section. Id. at § 1396r-8(k)(6).

152. The three compendia identified in subsection (g)(I)(B)(i) are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the DrugDex Information System. *Id.* at § 1396r-8(g)(l)(B)(i).

153. Similarly, off-label uses of drugs qualify as "medically accepted indications" for Medicare reimbursement only if they are supported by the aforementioned drug reporting compendia.

154. DrugDex is a proprietary information service provided by a division of the Thomson Reuters corporation. DrugDex is unique in that it is designated by the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 352(f)(1), the FDA Modernization Act of 1997 and FDA implementing regulations as a statutory compendium, and is the only such compendium that continues to publish detailed clinical information pertaining to pharmaceutical products.

155. Discussions of "therapeutic uses" for all drugs approved by the FDA are found within Section 4.5 of the DrugDex entry for that drug. These reviews include both FDA-approved and off-label indications. Material cited with respect to off-label indications can be used by the Centers for Medicaid and Medicare (CMS) in making decisions about the eligibility of claims made for reimbursement of the cost of program beneficiaries' prescription drugs. The specific content of DrugDex recommendations is therefore critical to reimbursement.

156. Upon information and belief, DrugDex and the other medical compendia, do not support the off-label uses promoted by GSK for GSK's drugs identified herein.

157. GSK knew or should have known the Medicaid and Medicare regulations governing prescription drug reimbursement and yet GSK intentionally marketed its drugs for off-label, non-medically accepted uses. As a result, physicians were induced to prescribe GSK drugs for off-label, non-medically accepted uses to beneficiaries of healthcare programs funded by the

government plaintiffs. As a direct result of GSK's influence on the prescribing habits of physicians, GSK intended to and did cause billions of dollars in false claims to be submitted to healthcare plans funded by the government-plaintiffs. Indeed, it was GSK's purpose and intent in marketing its drugs off-label for non-medically accepted uses to cause these false claims to be submitted to Medicaid, Tricare and the other government-funded healthcare programs identified herein.

158. For the purposes of this Seventh Amended Complaint, off-label use and non-medically accepted indication have been and shall be used interchangeably.

C. Health Care Programs Harmed by GSK's Unlawful Off-label Promotions.

159. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other health care programs, including but not limited to Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, the Federal Employees Compensation Act Program, 5 U.S.C. § 8101 *et seq.*, the Bureau of Prisons, State Legal Immigrant Assistance Grants and the Indian Health Service, the Department of Defense, the Department of Labor, and the Public Health Service Entities.

160. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. See, eg., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

161. For example, the VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

1. Medicare and Medicare Part D

162. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. The health insurance provided to beneficiaries of the Medicare insurance program is paid in whole or in part by the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of needy classes of individual healthcare patients pursuant to federal regulation. Medicare serves approximately 43 million elderly and disabled Americans.

163. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare ("Medicare Part D").

164. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. The Medicare Prescription Drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k) (as described above).

165. The first stage of the Medicare program, from May 2004 through December 2005, permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program.

166. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all beneficiaries, with low-income individuals receiving the greatest subsidies.

167. Coverage of prescription drugs under Medicare Part D is subject to the same regulations as coverage under the Medicaid Program described above

168. Upon information and belief, during the time period relevant to this Complaint, the off-label uses of the drugs identified in this Complaint promoted by GSK were not eligible for reimbursement from Medicare because those off-label uses were neither listed in the labeling approved by the FDA nor included in any of the drug compendia specified by statute.

169. As a direct, proximate and intended result of the conduct of GSK's alleged herein in violation of the federal FCA and the analogous laws of the Plaintiff States, the Medicare and Medicare Part D programs have been damaged.

2. The Railroad Retirement Medicare Program

170. The Railroad Retirement Medicare program is authorized by the railroad retirement act of 1974, at U.S.C.A. §231 *et seq*. It is administered through the United States Railroad Retirement Board, "RRB," and furnishes Medicare coverage to retired railroad employees.

171. As a direct, proximate and intended result of the conduct of GSK's alleged herein in violation of the federal FCA and the analogous laws of the Plaintiff States, the RRB program has been damaged.

3. Federal Employee Health Benefit Plans

172. The Federal Employees Health Benefits Program ("FEHBP") is administered by the United States Office of Personnel Management ("OPM") pursuant to 5 U.S.C.A §8901 *et seq.* and provides health care coverage to federal employees, retirees and their dependants and survivors

173. As a direct, proximate and intended result of the conduct of GSK's alleged herein in violation of the federal FCA and the analogous laws of the Plaintiff States, the FEHBP program has been damaged.

4. Tri-Care

174. The Tri-Care program, formerly, CHAMPUS, is administered by the United States Department of Defense through its component in agency, CHAMPUS, under the authority of 10 U.S.C.A. §§1071-1109. It is a health care program that provides for care in civilian facilities for members of the uniformed services and their dependents. Pursuant to 38 U.S.C.A. §8126, and the regulations based there on, drugs furnished by drug manufacturers to the Department of Defense must be furnished at the best price.

175. As a direct, proximate and intended result of the conduct of GSK's alleged herein in violation of the federal FCA and the analogous laws of the Plaintiff States, the Tricare program has been damaged.

5. The Veterans Administration

176. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") is a comprehensive health care program in which the VA shares the cost of covered health care services and supplies with eligible beneficiaries. The program is administered by Health Administration Center and our offices are located in Denver, Colorado. In general the CHAMPVA program covers most health care services and supplies that are medically and psychologically necessary.

177. Due to the similarity between CHAMPVA and the Department of Defense ("DoD") Tri-Care program the two are often mistaken for each other. CHAMPVA is a Department of Veterans Affairs program whereas Tri-Care is a regionally managed health care program for active duty and retired members of the uniformed services, their families and survivors. In some cases a veterans may look to be eligible for both/either program on paper.

However, military retirees, or the spouse of a veteran who was killed in action, are and will always be Tri-Care beneficiaries.

178. The VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

179. As a direct, proximate and intended result of the conduct of GSK's alleged herein in violation of the federal FCA and the analogous laws of the Plaintiff States, the CHAMPVA program has been damaged.

6. Other Programs Harmed

180. The other federally-funded healthcare programs harmed by GSK's off-label marketing include the Federal Employees Compensation Act Program, 5 U.S.C. § 8101, *et seq.*, the Bureau of Prisons, the Indian Health Service, and the State Legal Immigrant Assistance Grants program.

181. The Indian Health Service (IHS), an agency within the Department of Health and Human Services, is responsible for providing federal health services to American Indians and Alaska Natives. The provision of health services to members of federally-recognized tribes grew out of the special government-to-government relationship between the federal government and Indian tribes. This relationship, established in 1787, is based on Article I, Section 8 of the Constitution, and has been given form and substance by numerous treaties, laws, Supreme Court decisions, and Executive Orders. The IHS is the principal federal health care provider and health advocate for Indian people, and its goal is to raise their health status to the highest possible level.

182. Pursuant to 42 U.S.C.A. 2002 *et seq.*, the Secretary is authorized to enter into contracts with independent providers to furnish health services to Native Americans whenever

the Secretary determines that independent providers can better meet the population's need. This includes pharmacy benefits.

183. The IHS currently provides health services to approximately 1.5 million American Indians and Alaska Natives who belong to more than 557 federally recognized tribes in 35 states. The health services provided by the IHS include prescription drug benefits.

184. Relators are informed and believe and based thereon allege that the United State also furnishes funds which several States use to pay for such drugs pursuant to State Legal Immigrant Assistance Grants ("SLIAG"), 8 U.S.C.A §1255A; 45 C.F.R. §402.10.

185. As a direct, proximate and intended result of the conduct of GSK's unlawful marketing conduct in violation of the federal FCA and the analogous laws of the Plaintiff States, the Federal Employees Compensation Act Program, the Bureau of Prisons, IHS, and the SLIAG program have been damaged.

D. The Anti-Kickback Statute and GSK's Systematic Statutory Violation In The Marketing and Sale of Prescription Medications

186. The anti-kickback statute makes it a criminal offense knowingly to offer, to pay, to solicit, or to receive any remuneration to induce or reward referrals of items or services reimbursable by any Federal health care program. 42 U.S.C.A. §1320a-7b. The law helps to ensure the independent decision-making process of physicians which could be subverted by the use of monetary inducements, and helps to ensure the safety of the public.

187. Any time remuneration is offered or paid with the intent to induce or reward referrals of items or services payable by any Federal health care program, the Anti-Kickback Statute is violated. For purposes of the Anti-Kickback Statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. If a drug company offers to pay or pays remuneration to a health care practitioner with the intent to

induce that practitioner to prescribe one or more of its products, the Anti-Kickback Statute is violated.

188. All direct participants in Federal health care programs, to be eligible for reimbursement of items and services, including all health care providers, pharmacies and pharmacy benefit managers, must agree, explicitly and implicitly, to abide by all laws pertaining to these programs, including the anti-kickback statute and the law relating to the misbranding of prescription medications. All pharmaceutical manufacturers, including GSK, are aware of this provision. Thus, a pharmaceutical company which has intentionally offered, paid, or solicited remuneration to induce physicians and other health care providers to prescribe drugs reimbursed by any Federal health care program has violated the provisions of both the Anti-Kickback Statute and the False Claims Act.

189. Many of the Plaintiff States have enacted their own Anti-Kickback Statutes, as articulated in each such Plaintiff State's claim for relief in the subsection of this Seventh Amended Complaint. The same conduct giving rise to violations of the federal Anti-Kickback Statute also give rise to violations of the parallel state provisions.

E. GSK'S Use of "FaxBacks" and Medical Journal Articles For Off-Label Promotion In Violation of the FDCA and The False Claims Act

190. From at least 1997 and continuing through to the present, GSK utilized a system called the "FaxBack Service" to enable its sales representatives to distribute medical literature, including journal articles, editorials, retrospectives and other ostensibly peer-reviewed scholarly articles to physicians and other health care practitioners.

191. Effectively, GSK circumvented the FDCA's rigorous rules concerning how such information is used in the promotion and marketing of pharmaceutical products that have not yet been approved by the FDA.

192. The concerns addressed by the FDCA regulations include a lack of fair balance, appropriate presentation of opposing studies, adequate warnings of possible adverse reactions, adequate information concerning proper dosage and administration and other vitally important requirements of the FDCA and its implementing regulations.

193. GSK provided each of its sales representatives with "FaxBack Service" books containing articles supporting the off label use of its prescription medications, along with a toll free number.

194. Although the top page of these articles often contained the phrase "Not for Distribution," the toll free facsimile number was intended to enable the convenient distribution of copies of the documents to physicians.

195. Notably, the FaxBack Service books did not comply with the requirements of the aforementioned FDCA requirements concerning the presentation of alleged scholarly articles. Even more disconcerting, was the fact that the FaxBack books contained information that was unsupported by clinical test data and in some instances erroneous.

196. Until at least April 27, 2004 when GSK's COPD Marketing Division issued a memorandum setting forth a new procedure discouraging sales representatives from taking the "FaxBack" indices with them to meetings with health care practitioners, sales reps were encouraged to take the books with them to detail physicians.

197. At a meeting of the Western Sector sales force in Phoenix early in 2000, former Western Region sales head Roger Hawley told his employees that "[W]e had to fight with legal [GSK's legal department] a long time so that you guys could carry these fax backs with you, so utilize them as much as possible in your sales efforts." GSK maintained records on each sales representative's use of FaxBack documents, and it was well known among GSK's sales

representatives that bonuses were most likely to accrue to sales representatives that utilized the FaxBack service with the greatest frequency.

198. Plainly, GSK's real purpose in utilizing the so-called "FaxBack Service" scheme was to circumvent the requirements of the FDCA by unlawfully and fraudulently taking advantage of the safe harbor provided by 21 USCA § 557(a) and 21 CFR § 99.1(2)(b). Because the technical requirements for the dissemination of medical literature and other documents supporting non-approved uses do not apply to any documents disseminated in response to an 'unsolicited' request from a health care provider, the Faxback Service was uniquely designed to circumvent federal marketing regulations.

199. Although on the surface the documents were supposed to be provided only upon the unsolicited request of a health care practitioner, GSK carefully indoctrinated its work force to make the record appear that it was the doctor, rather than the sales person, who brought up the off-label topic. For example, training given to sales representatives in the off label use of Advair for the treatment of COPD included reference to a specific "FaxBack" article supporting that use of the drug (e.g., FaxBack "428"), and respiratory therapy sales reps were trained in leading the conversation with the physician from the approved use, asthma, to the unapproved use, treatment of COPD.

200. When detailing physicians and using FaxBack resources, GSK sales representatives were given both specific training on off label uses of GSK drugs and methods of getting the physicians to speak about these other uses, including written examples of questions that doctors might ask, coupled with specific follow up comments and ending always with the "Closing: give dosing and ask for business."

201. Another strategy employed by GSK to increase distribution of off-label faxbacks, was the frequent utilization of special “sales aids” consisting of power point programs like the Valtrex Power Point Presentation from 2000 which significantly expanded potential therapeutic uses beyond the FDA approved indication. Other examples include slides for use in “peer-to-peer” physician presentations, and simple demonstrative aides, such as a series of laminated cards or documents that would, in the natural progression of a discussion with a physician, permit the sales representative to talk to the physician about the off label use and to produce a copy of a relevant "Faxback" study.

202. An even more egregious example of the use of off-label articles to generate prescriptions, was GSK’s distribution of a paper published in the European Respiratory Journal by B.R. Celli entitled “Standards for the diagnosis and treatment of patients with COPD; a summary of the ATS/ERS position paper”. The article was distributed prior to the receipt of FDA approval for COPD and contained a great deal of information about different aspects of Chronic Obstructive Pulmonary Disease, emphasizing the treatability of COPD, that smoking is a factor, and that inhaled corticosteroids, like Advair, were recommended for use in treatment.

203. Although GSK included the usual "Not for Promotional Use" disclaimer on the Celli article, the only possible use for this information was to permit sales representatives to distribute the scholarly article to market Advair in the treatment of COPD prior to its approval.

204. In order to simplify distribution of the FaxBack documents, each GSK sales representative was provided with a notebook computer containing a software program (“Passport”) giving the representatives the ability to send medical literature on off label uses directly to physicians, with or without a request from the physician. Prior to using the Passport

system, sales reps were trained, via CD Rom, on exactly how to forward the medical information.

205. Clearly aware of the illegality of their off label marketing strategies and FaxBack program, GSK's management made a conscious, and deliberate effort to cover up their actions. As Relator Hamrick can attest, at a management training program in July 2002, he was instructed by a manager-in-training that, with respect to the detailing of Lamictal to psychiatrists for bipolar disorder, the record of every contact report should automatically include the phrase "Dr. inquired about bipolar disorder" regardless of whether that request was made.

206. Ultimately, the FaxBack program enabled the GSK sales force to distribute thousands of off-label faxback materials to health care providers over the period of this complaint.

VII. GSK'S OFF-LABEL MARKETING OF ADVAIR

207. Advair is a "combination" drug that uses GSK's patented "diskus" dispensing device, a plastic disk-shaped mechanism that purportedly permits the patient to take the medication orally in a more effective manner than a traditional inhaler.

208. The actual medication itself is a combination of an anti-inflammatory corticosteroid known as fluticasone propionate, which is also the active ingredient in GSK's Flovent and Flonase, with a long acting beta agonist, ("LABA,"), salmeterol, the active ingredient in GSK's Serevent, which is a bronchodilator.

209. On August 24, 2000, the FDA first approved Advair Diskus for the inhalation for the long term twice daily maintenance treatment of asthma in patients 12 years of age or older. It was approved for this use in the following strengths: 100/50; 250/50; 500/50.

210. Advair received its first pediatric indication on April 21, 2004, when the FDA approved Advair Discus 100/50 for use in children aged 4-11 with asthma.

211. Additional approvals for Advair and COPD are discussed *infra*.

212. The medical community has long had significant concerns over the potential dangers of long acting beta agonists, also known by the acronym "LABA," including a concern that the drug may ‘mask’ severe inflammation, as well as a concern that use of the drug may lead to hypersensitivity to the stimulants that create an asthmatic reaction. For that reason, it has been generally accepted in the medical community, and *publicly* acknowledged by GSK, that Advair should only be used when a patient’s symptoms are not being adequately controlled by another less dangerous medication, or when a patient’s asthma symptoms are significantly severe enough to warrant such treatment.

213. Following the Advair launch in August 2000, GSK inundated the marketplace with promotional materials by sending nearly 2,300 sales representatives to 70,000 physicians in the first five days alone. Even before the launch, as far back as 1999, GSK sales representatives were actively promoting Advair at the direction and instruction of GSK.

214. According to its internal half year review in 2001, GSK reported that in just the first 12 weeks after its launch, Advair achieved an astounding 12% market share, and after 2 months, Advair sales had reached $100 million, no doubt in part due to the improper pre-launch marketing.

215. The Advair promotional schemes described herein orchestrated by GSK executive management on a nationwide basis were intended to and did cause the submission of false reimbursement claims to government-funded healthcare programs such as Medicaid and Tricare for off-label uses of Advair that were not supported by the medical compendia.

A. GSK'S Off-Label Marketing of Advair for the Treatment of Mild Asthma

216. In 1997, 2002 and 2007, in an effort to assist clinicians in decisions about appropriate diagnosis and treatment modalities for asthma patients, the National Heart Lung and Blood Institute ("NHLBI") published "Guidelines for the Diagnosis and Management of Asthma."

217. In each of the three publications of the Guidelines, the NHLBI has consistently divided asthma severity into four groups: (1) intermittent, (2) mild persistent, (3) moderate persistent and (4) severe persistent.

218. Notably, the NHLBI guidelines consistently provide that only moderate to severe persistent asthma should be treated by means of combined ICS/LABA medications to avoid unnecessary exposure of patients with mild or intermittent asthma to the well-documented health risks associated with LABAs.

219. In fact, of paramount concern is the fact that on February 18, 2010, the FDA released a safety announcement and 460 page document regarding the safety of LABAs. *7AC 0000071-0000073.*

220. Specifically, through meta-analysis of over 100 trials, the FDA found an "increased risk of severe exacerbation of asthma symptoms, leading to hospitalization in pediatric and adult patients as well as death in some patients using LABAs for the treatment of asthma".

221. As a result of the alarming statistics, the FDA has issued new recommendations applying only to the use of LABAs in the treatment of asthma. These recommendations include the directive that "LABAs should only be used in long term patients whose asthma cannot be adequately controlled on asthma controller medications" (emphasis added).

222. Such a warning specifically precludes the use of LABAs in patients with mild asthma and, as such, GSK's off-label marketing for mild asthma continues to put countless patients at risk.

223. As part of their effort to obtain an FDA indication for Advair and asthma, GSK employees, including Dr. Tushar Shah made presentations to the FDA's Pulmonary and Allergy Drugs Advisory Committee (PADAC) including one on November 23, 1999.

224. In his presentation, Dr. Shah asserted that the trial study data supported the use of Advair for moderate to severe persistent asthma and affirmatively represented that the drug would not be appropriate for use in patients' intermittent or mild asthma and that use would be consistent with NHLBI guidelines.

225. Based on the findings of the PADAC, GSK was required to change the labeling on Advair to remove ambiguities as to appropriate patient populations and more accurately reflect the populations that participated in the clinical studies. The resultant label, approved by the FDA, specifies that Advair is for use only in patients with asthma severe enough to require combination therapy. The indicated patient population, according to GSK's own testimony, corresponds only to moderate/severe asthma.

226. Despite the testimony and acknowledgement of its own employees, including Dr. Shah, that Advair was not appropriate for use in patients with mild asthma, upon receiving the prized FDA approval, GSK undertook an aggressive marketing campaign for Advair for *all* forms of asthma—including mild asthma.

227. As part of both the Advair campaign and their regular course of business, sales representatives routinely documented their conversations with physicians on visits in their

contact reports. A sampling of the contact reports generated within the first three (3) months of the Advair launch plainly indicate the push toward use for mild asthmatics.

228. GSK's insistent sales pitch to mild asthma patients exemplifies their complete and total disregard for the fact that it lacked any clinical trials with mild asthma patients and, consequently, possessed no scientific basis to support the use of Advair in a patient group that comprises approximately 1/3 of the total number of asthma patients in the United States.

229. In fact, as part of an Advair Evaluation in November 2001, Relator Hamrick was actually instructed to "clarify doctor's opinion on 'well controlled patients,'" essentially questioning physicians about who they consider to be a well controlled patient and suggesting that their patients are not as controlled as the physicians think they are. *7AC 0000074.* Such actions were calculated to increase off-label Advair prescriptions for mild asthmatics.

230. As part of an incentive program to increase Advair sales, in November 2002 GSK provided a document promising sales reps handsome rewards for high sales numbers, and proclaimed that, "[t]he prevailing thought on the U.S. Asthma Market continues to shift towards a market that is comprised of a small proportion of patients who fall into the intermittent category and a significantly larger proportion of the asthmatic population that falls into the persistent category."

231. While providing the incentive programs, GSK simultaneously produced marketing program materials including sales aids like the "Freedom Detail." *7AC 0000075-0000080.*

232. This particular detail aid was launched in October 2001 and used continuously throughout 2002 and much of 2003. The detail aid itself consisted of a pamphlet featuring the slogan "Freedom to do More" with verbiage that the Advair Diskus "Gives patients the freedom

to do more of what they want to do"; and that it "improved symptoms that may interfere with normal daily activities." All of these assertions were made without explaining that Advair was indicated for use in moderate to severe cases only. *7AC 0000077.*

233. In the Freedom detail aid, GSK utilizes pictures of "patients" and attempts to convince physicians that their mild asthma patients were being overlooked and underestimated and that Advair is an appropriate remedy for all people who want to "do a lot more physical and outside-type things, like walking my dogs and riding bikes with my kids." The sweeping commentary by alleged Advair users once again obfuscates the fact that Advair is only indicated for moderate to severe asthma and suggests its applicability across the board for all asthma sufferers.

234. In addition to the patient vignettes featured throughout the Freedom Detail, GSK includes summaries of dubious studies by Drs. Anne Fuhlbrigge and William Calhoun to further suggest the use of Advair in cases of mild asthma is in accordance with NHLBI Guidelines.

235. The Fuhlbrigge study was actually based on a telephone survey of presumed asthma patients and, instead of suggesting adherence to the NHLBI Guidelines, proposed Dr. Fuhlbrigge's own severity classification system. Whereas Fuhlbrigge made presumptions and drew flimsy conclusions based on a telephone survey, the Calhoun "study" isolated the placebo patients in a GSK clinical trial who were, as adjudged by spirometric testing, moderate to severe asthma patients, and on that basis concluded that "mild" asthma patients were being overlooked and should be prescribed Advair.

236. Despite the absolutely nonsensical and scientifically unreliable "data" produced from the aforementioned Fuhlbrigge and Calhoun studies, GSK's respiratory sales force was

trained to learn and produce summaries of these two findings by rote memorization in order to convince physicians to increase their script writing for mild asthma.

237. As GSK continued marketing Advair for mild asthma, they began to face some resistance from physicians who were reluctant to prescribing the drug to patients with mild asthma. To that end, in conjunction with its "Freedom Detail" marketing plan, GSK provided workshop materials to overcome physician's objections to prescribing Advair for mild asthma and, in 2002, distributed a Respiratory Marketing Resource to respiratory sales representatives nationwide providing role playing strategies and tips on how to sell Advair to physicians who objected that it was not appropriate. *7AC 0000081-0000114.*

238. The "Handling Resistance" section of the Respiratory Resource Guide included situations like the following:

> Objection: Can I use ADVAIR DISKUS as initial maintenance therapy, because it is not recommended in the guidelines?
> Solution: Doctor, ADVAIR DISKUS can be used first-line in patients who are currently on short acting $beta_2$-agonists alone, who need treatment with two maintenance therapies…Remember, asthma is a disease with two main components and to provide optimal control for many patients, both the inflammation and bronchoconstriction need to be treated.

7AC 0000090.

239. The scenario goes on to suggest the use of the scientifically questionable Calhoun study discussed below as a source of proof for advocating the use of Advair in patients with mild asthma and as a first line treatment, both uses which are completely outside the guidelines as propounded by the NHLBI. Another resistance scenario from the same Selling Guide coached sales representatives to still push Advair for mild asthma despite a physician specifically stating his patients are mild asthmatics and have no need for maintenance therapy. The response focuses on the oft used marketing angle that asthma is "underestimated":

> Objection: Most of my patients with asthma are mild and do not need maintenance therapy.
> Solution: According to a large survey, overall asthma control is not optimal for many patients in the United States. For example, this survey found that patients and healthcare providers alike grossly underestimated morbidity associated with asthma. This is due in part to the fact that asthma is a variable and unpredictable disease and can be aggravated by many factors…

7AC 0000091.

240. Coached scenarios addressing legitimate physician resistance serve only to reinforce the fact that GSK was not only marketing off-label, they were fully engaged in a harmful campaign of misinformation.

241. Indeed, in addition to the coaching workshops, the Resource Selling Guide also directed reps to utilize Faxback #418 which advocates for the use of ADVAIR DISKUS as initial therapy. Yet another thinly veiled attempt by GSK to gain market share for Advair through the prescription of unapproved uses. *Id.*

1. GSK'S Improper Use of Speakers and National Thought Leaders to Promote the Off-Label Marketing of Advair for Mild Asthma

242. GSK paid its "thought leaders" and "key opinion leaders" to promote the idea that mild, intermittent asthma is an often mistaken diagnosis for moderate or even severe persistent asthma, with the intent of increasing the off-label, non-medically accepted use of Advair, despite the risks associated with the use of this drug for intermittent asthma.

243. Despite both the findings of the SMART trial, and the subsequent additional warning put on the Advair label by the FDA, GSK continued to obscure the lines between mild and moderate/severe asthma through its use of paid CME presentations by "key opinion leaders" and "thought leaders".

244. In addition to the use of its thought leaders for CME presentations, GSK used its own employees to draft peer-reviewed literature on treatment of asthma in such a way as to make it likely that physicians would prescribe Advair even for their patients with mild or moderate intermittent asthma.

245. Among GSK's favored authors was Dr. David S. Pearlman, who published a study in 2004 entitled "Efficacy and Safety of Fluticason Propionate/Salmeterol HFA 134A MDI in Patients with Mild-to-Moderate Persistent Asthma." The article was based on a GSK clinical trial that took place in 2000, and although the study purported to be on "mild" patients, only moderate to severe patients by NIH spirometric testing were enrolled.

246. The aforementioned use of thought leaders to further the off-label intentions of GSK is exemplified in CME materials drafted by thought leader Dr. Robert Nathan, and supplied to Relator Hamrick. *7AC 0000115-0000118.*

247. These April 2004 materials, drafted by Dr. Nathan, were entitled "Asthma: Diagnosis Mild? Look Again," and contained charts, including one that is little more than a series of squiggly lines with absolutely no data reference, suggesting that people with mild or intermittent asthma may actually have persistent, or even severe asthma. The use of such purposefully vague materials, coupled with the Dr. Nathan's name recognition, served only to further GSK's off label schemes. *Id.*

248. Interestingly, on information and belief, despite his rampant off label promotion for mild asthma, Dr. Nathan continues to earn exorbitant fees as a key opinion leader and speaker including $35,700 in the second quarter of 2009.

249. Physician script writing and brand loyalty can also be influenced by grants and preceptorships, even when the physician makes a concerted effort at neutrality. Evidence of the

influence of these cash incentives can be seen in the contact reports of the sales representatives as well as in internal documents.

250. Dr. David S. Pearlman, a respiratory specialist from National Jewish Hospital, was heavily courted by GSK for the promotion of Serevent and Advair between 2002 and 2005. During this time, contact reports reflect GSK actively engaging Dr. Pearlman to promote Advair for mild asthma.

251. In 2004, Dr. Pearlman published an article entitled "Efficacy and Safety of Fluticasone Proprionate/Salmeterol HFA 134A MDI in Patients with Mild-to-Moderate Asthma" (*Journal of Asthma*, 2004). Of note however, the clinical study on which this article was based only tested patients who suffered from moderate to severe asthma. In a call note dated February 12, 2002, Dr. Pearlman "Spoke about his up coming article Advair vs. Singular in mild to mod pts."

252. Upon review of the contact reports for Dr. Pearlman, a GSK sales representative either met or communicated with the physician on at least 45 occasions between January 2002 and July 2003. What follows is a sampling of the contact reports generated as a result of the visits with Dr. Pearlman and the documentation of GSK's efforts to induce him to become a promoter of Advair for mild asthma.

- **2/12/02:** A GSK sales rep. met with Dr. Pearlman and the doctor questioned the integrity of some of the data, fax-back studies involving safety concerns about Salmeterol (Serevent);

- **3/13/02:** Dr. Pearlman responded to an email and expressed an interest in a research study sponsored by GSK.

- **03/29/02:** Dr. Pearlman told the GSK sales rep. that 'they are getting pts. Who are on Advair into their trials by paying very well, also some pts want to help. Pts don't always leave on Advair, often a note is put in their file for their PCP to decide.'

- **06/18/02:** A GSK sales rep. met with Dr. Pearlman to discuss Salmeterol and suggested that Pearlman should meet with Malcolm Johnson (a GSK researcher from the United Kingdom) and Denny Clifford (a physician and paid "thought leader").

- **06/28/02**: Dr. Pearlman was detailed by a GSK sales representative who left the following large quantities of samples of Advair Diskus, Augmentin, Flovent and Serevent: (1.) a 5 months supply of Advair 100/50; (2.) a 9 months supply of Advair 250/50; (3.) *a 10 months supply of Advair 500/50*, (4.) 6 10-day courses of therapy of Augmentin; (5.) a 2 years supply of Flonase; (6.) A 12 months supply of Flovent 110mcg; (7.) a 6 months supply of the Flovent 22mcg; (8.) a 12 months supply of Flovent 44 mcg; (9.) a 3 months supply of Serevent diskus; and (10.) a 9 months supply of Serevent aerosol.

- **07/28/02:** GSK arranged a 'roundtable discussion' with Malcolm Johnson, GSK paid 'thought leader' Dr. Bob Nathan, Denny Clifford, Rob Lapidus and Dr. Pearlman.

- **07/28/02:** Dr. Pearlman expressed his appreciation of GSK's unidentified sales representative, "evidence that the initially tenuous relationship has progressed substantially in a positive direction."

- **09/12/02:** Dr. Pearlman suggested that GSK consider re-establishing post-study meetings, indicating that he and other researchers 'have a vested interest in the outcome of the studies they participate in and feel that this type of outreach by GSK could go a long way in improving/or solidifying good relations between investigators and pharma..' and he 'feels that the RMS [Regional Medical Scientist from GSK] could fill the gap if GSK does not want to have post-study updates with investigators.' At the same time, the sales rep. reported that he felt Dr. Pearlman was giving him a hint that if relations between he and GSK did not improve, his loyalties may swing to another company when another combination agent [such as Advair] entered the market.

- **02/20/03:** Dr. Pearlman reviewed his expectations for receiving samples from GSK with a GSK sales representative and indicated to the representative that GSK was not paying sufficient attention to this issue.

- **February of 2003:** There were a series of meetings between Dr. Pearlman and his GSK sales representative, including a lunch with District Manager Ned Schneidewind, who handed Dr. Pearlman a grant check for $25,000 in the presence of GSK sales representative Peter Copeland.

- **03/04/03:** Shortly after being given the grant check and airing his issues concerning additional free samples, GSK's sales representative assigned to Dr. Pearlman 'talked

about him doing a spring lecture to PA's, doctors, he was very happy to accept the invite' and inquired about what the physician's assistants 'wanted to hear.

a. GSK Employed Ghostwriters to Author Favorable Journal Articles for Advair and Mild Asthma

253. The Advair marketing campaign also utilized GSK employees to ghostwrite medical journal articles in a way that implied that Advair was safe and effective for all asthma disease states, including mild asthma. GSK employees active in drafting Advair articles included Kim Poinsett-Holmes, Trudy Perdergraft as well as Dr. Paul Dorinsky and Katherine Rickard. Articles drafted by these GSK 'ghostwriters' were utilized as 'faxbacks' and intended to influence physicians to prescribe Advair for all forms of asthma.

254. By way of example, an article[3] supplied to GSK's Advair sales representatives nationwide, and heavily emphasized in GSK's confidential Respiratory Selling Resource, was 'authored' by Dr. William J. Calhoun but drafted by GSK employee Kim Poinsett-Holmes; the article implied that Advair was appropriate for mild, persistent asthma. *7AC 0000119-0000123.* This article received a vehement, public objection by another researcher, Dr. Jonathon Ilowhite, who pointed out that the study referenced in the article actually *excluded* participation by patients with mild, persistent asthma.

2. GSK'S Off-Label Marketing of Advair in Pediatrics

255. Advair did not receive a pediatric indication until April 2004. However, the confidential 2002 Respiratory Selling Resource contained verbatims and selling points for marketing off-label and pre-approval to children. *7AC 0000114.*

256. Specifically, regardless of the lack of an indication, sales representatives were in fact provided with a single journal article advocating the safety and efficacy of Advair in

[3] Calhoun *et al.*, Am J Respir Crit Care Med Vol 164. pp 759–763, 2001.

children under 12 entitled: "Salmeterol/Fluticasone Propionate in Combination in a Diskus Inhaler Is Effective and Safe in Children With Asthma," N.J. Van Den Berg, M.D. *et al.*, *Pediatric Pulmonology* 30:97-105 (2000).

257. The clinical study referenced in this article was a comparison between a group of pediatric patients taking Salmeterol and Fluticasone Propionate in separate diskus dispensers with a group of pediatric patients taking precisely the same medications, Salmeterol and Fluticason Propionate, in the same dosages in a single diskus. However, the study was used by GSK's sales representatives to tout the overall safety and effectiveness of Advair for children in the 4 to 11 year age group long before the FDA approved the drug for use in that age group.

258. The Van Den Berg article was also captured and promoted as Faxback #413 "Use of ADVAIR DISKUS in pediatrics" and was made available to the sales force for use in promoting the safety and efficacy of Advair over salmeterol alone.

259. Relator Hamrick will attest that, from the very beginning of the Advair launch, GSK's Advair sales representatives were given the following verbatim recitation to deliver to physicians and pediatricians:

> Doctor, Advair is indicated for children 12 yrs old or greater, however the individual components are indicated down to age four. It is only because the studies for Advair's approval didn't include children under age 12 that it has not yet been approved for that age group, but there are plenty of studies for both Serevent and Flovent in children down to age 4.

260. Notably, an FDA pediatric advisory committee concluded that the risks of salmeterol outweighed the benefits in the general population, and only by a narrow vote determined that Advair may be used in the 4 to 12 age group, and only when treatment with inhaled corticosteroids alone has proven inadequate.

261. In addition to the use of journal articles and FaxBacks, contact reports generated by sales representatives also indicate the prevalence of off-label Advair detailing to pediatric specialists including the following entries:

- Dr. Mark H. Pearlman of Aurora, Colorado was detailed for Advair Diskus and Flonase by a GSK sales representative who noted: "Real life, kids don't come in before allergy season, don't come in when they get symptoms, wait until mom is going crazy and brings them in, want fast relief."

- May 16, 2002, Dr. Spyridon G. Papadopoulos of Denver, Colorado was detailed by a GSK sales representative for Advair Diskus and Flonase with a note that "Had just put his 1st pt on Advair, went over adv on device for child parent."

- May 30, 2002, Dr. Gerald T. Fincken was detailed by a GSK sales representative on Advair Diskus with a note that indicated "do nurses allow albuterol with the child? PNAR – concern for kids is a reality. aug- - mac."

- June 10, 2002, Dr. Scott Sagel of Denver, Colorado was detailed by a GSK sales representative for Advair Diskus, Flonase and Serevent with the following note: "Adv in kids, refered [*sic*] to van [meaning the GSK sponsored "Breath Better Bus" that visited neighborhoods with free spirometry testing], and faxback availability, docs started detailing each other on who and why they use advair, it was great, reviewed formulary status, remind of fnase [flonase]- uses ventolin himself and talked how he tries to keep track or use mdi to the last drop sees how diskus is easier to use and monitor."

- June 2, 2002, Dr. Andrew H. Liu of Denver, Colorado was detailed by a GSK sales representative for Advair Diskus and Flonase with a discussion of pediatric data, which, allegedly, the doctor "brought up." GSK sales representatives were frequently reminded by their supervisors that they should always suggest that it was the physician who first broached the off-label topic.

- June 27, 2002, Dr. Liu was again detailed by a GSK sales representative for Advair Diskus and Flovent with a note indicating that "Discussed new asthma guidelines and changes for peds. Dr. Kerby uses ICS [Inhaled Corticosteroids] as much as possible in young kids despite age indications."

- September 23, 2002, Dr. Connie L. Corcoran was detailed by a GSK sales representative for Advair Diskus and Flonase with a note indicating: "Thinks Advair is good choice for children 8+, for correct device usage."

- October 22, 2002, Dr. Pearlman was again detailed by a GSK sales representative for Advair Diskus and Flonase with a note indicating: "Also presented flonase growth data, aggressive safety trial, addressed safety in young kids vs nasonex

age 2, flipped piece to remind dr of 25% > effect in sar [seasonal allergic rhinitis] than nasonex. ES reminder, and dr asked about 600 tabs." Flonase was not indicated for children aged 2.

- October 22, 2002 Dr. Carol F. Reddy of Aurora, Colorado was detailed by a GSK sales representative on Advair Diskus and Flonase with a note indicating: "Advair (persistent asthma and use in Kids - she is more comfortable rxing it) Flonase best choice (efficacy-safety)."

- October 29, 2002 Dr. Roxann M. Headley of Aurora, Colorado was detailed by a GSK sales representative on Advair Diskus with a note indicating: "Very supportive of prods. Looking for ADV for a few kids. Reminder on CDC guidelines for persistent AOM, FLN vs. NSX tag line."

- November 22, 2002 Dr. Michelle K. Stanford was detailed by a GSK sales representative on Advair Diskus and Flonase with a note indicating: "Great discussion of advair to pt. Dr. req advair 500/50 [samples], s [states] that she has some very severe pt who needs higher dose on occas. Usually some of the larger kids. Gave form and PNAR indic for flonase."

- January 27, 2003, Dr. David Pearlman was detailed on "Serevent/COPD Market Development" with a note indicating he would be giving a talk on efficacy and safety of drugs for pediatric asthma in an evening symposia for allergy and asthma specialists and "would appreciate any pertinent info re salmeterol in this age group if GSK has any from the discontinued study or elsewhere."

- January 29, 2003, Dr. David C. Simon of Aurora, Colorado was detailed by a GSK sales representative on Advair and Flonase with a note indicating that he was "not altogether comfortable using Advair with age indication being at 12."

- January 11, 2003, Dr. Lee S. Thompson of Aurora, Colorado was detailed by a GSK sales representative on Advair and Flonase with a note indicating: that he was not comfortable using Advair either with children because of the age indication at 12 years of age.

- February 5, 2003, Dr. David Pearlman was again detailed by a GSK sales representative on Advair and Serevent with a note indicating that he would be giving a talk to a national group of physicians at a meeting of the American Academy of Allergy, Asthma and Immunology and asked the sales rep for "data/slides that may be pertinent to presentation...." The doctor indicated that he felt Salmeterol was "safe" and that studies reporting safety concerns "are reflective of too high of dose and Mds not treating individual patients." An FDA advisory committee eventually found that the benefits of Salmeterol for use in patients with asthma do not exceed the risks.

- March 4, 2003, Dr. Lee S. Thompson of Aurora was detailed by a GSK sales representative on Advair and Flonase with a note indicating that he felt more comfortable prescribing Advair although he was aware of the age limitation.

- June 11, 2003 Dr. Henry Milgrom of Denver, Colorado was detailed by a GSK sales representative on Advair, Serevent and Flonase with a note indicating that he needed slides on the safety of ICS (inhaled corticosteroids) in children for a presentation he intended to make to a group of physicians in Lodz, Poland.

- July 9, 2003, Dr. Sam Shimamoto, a new physician at National Jewish Hospital was detailed by a GSK sales representative on Advair and Flonase with a note indicating that the therapeutic specialty representative from GSK "gave him very nice review...." and discussed Advair in small amounts for pediatric patients, adding [W]ill schedule lunch for more time. Very friendly."

- July 10, 2003, Dr. Henry Milgrom was again detailed by a GSK sales representative on Advair and Flonase with a note indicating that they discussed his obtaining slides on the use of inhaled corticosteroids in children for a presentation he was making, although the sales representative was careful to add that the request was "unsolicited."

3. GSK Aggressively Targeted High Medicaid Markets for Off-Label Use of Advair

262. In July 1999, GSK initiated the Salmeterol Multi-center Asthma Research Trial ("SMART") with the primary goal of determining the potential association between Salmeterol (salmeterol is the long-acting $beta_2$-agonist component of Advair) and respiratory related deaths and life threatening experiences.

263. In the fall of 2002, GSK was notified by the Data Safety Monitoring Board, which oversaw the SMART study, that among the African American participants, "the study showed a statistically significant greater number of primary events and asthma-related events, including deaths, in patients taking salmeterol compared to those taking placebo".

264. As a result of these findings, GSK issued a "Dear Healthcare Professional" letter to healthcare providers on January 23, 2003 and again on August 11, 2003. *7AC 0000124.* Additionally, in August 2003, the following warning was added to Advair's label:

> Data from a large placebo-controlled US study that compared the safety of salmeterol or placebo added to usual asthma therapy showed a small but significant increase in asthma-related deaths in patients receiving salmeterol ... versus those on placebo [and] [S]ubgroup analyses suggest the risk may be greater in African-American patients compared to Caucasians (see WARNINGS).

265. The final safety warning ("Black Box" warning) for Advair was approved by the FDA in March of 2006.

266. Acting with blatant disregard of the notice they received in 2002, GSK continued to push its sales representatives to market Advair to high decile physician prescribers with a large African American patient base.

267. In fact, at a national meeting of "therapeutic respiratory specialists" held at the Peabody Hotel in Orlando, Florida, February 24th - 28th, 2003, **one month *after*** GSK sent a "Dear Healthcare Letter" advising of the concerning results of the SMART trial for the African American population, Relator Hamrick and his fellow reps were given a spreadsheet indicating the percentage of black Americans being prescribed Advair for asthma compared to total market share for cities throughout the West, including Denver, Colorado Springs, Seattle, Phoenix, Las Vegas, Honolulu, Portland, Tacoma, Olympia, Tucson, Pocatello, Idaho and Salt Lake City.

268. Mr. Hamrick, along with his fellow sales representatives, was informed that targeting both African Americans and Hispanics was essential in order to keep up with sales reps in other regions. To hammer the point home, California was highlighted as leading the nation in Advair sales because of that state's large population of African Americans and Hispanics on Medicaid. The messaging continued during district breakouts with John Foy, Jim Altreiter and Tom Tyma (then Market Development Managers for the region) coming by all of the districts and going over the spread sheet in depth.

269. At the same national meeting in 2003, the aforementioned breakout sessions were preceded by a lecture from Regional Vice President Fred Gregg to all of the regions, specifically concerning Medicaid targeting. Gregg emphasized that because there were no formulary restrictions with Medicaid, prior authorizations were not required. Additionally, Gregg explained, successful Medicaid marketing was the reason that California was leading the other regions.

B. GSK'S Off-Label Marketing of Advair for the treatment of COPD

270. On November 17, 2003, the FDA approved Advair Diskus **250/50** for the maintenance treatment of airflow obstruction in patients with Chronic Obstructive Pulmonary Disease ("COPD") *associated with Chronic Bronchitis*.

271. Five years later, on April 30, 2008, the FDA expanded the Advair Diskus **250/50** approval to be indicated for "the maintenance of airway obstruction and reducing exacerbations in patients with COPD, including bronchitis and emphysema."

272. A COPD exacerbation, which is included in the April 2008 Advair 250/50 indication, is defined as an "acute change in dyspnea, cough or sputum sufficient to warrant therapy change."

273. Advair Diskus 500/50 has never been FDA-approved to treat any aspect of COPD, whether it be associated with bronchitis or emphysema, nor has it been approved to treat COPD exacerbations. In fact, on August 9, 2007, the FDA deemed GSK's supplemental new drug application for Advair 500/50 for COPD "unapprovable."

274. There is no clinical data supportive of Advair 500/50 for use in COPD or its exacerbations. Rather, GSK's clinical trial data has demonstrated that Advair 500/50 is 1) no more efficacious than Advair 250/50 in the treatment of COPD and its exacerbations and that it

2) significantly increases the incidence of dangerous side effects including, but not limited to, lower respiratory infections, serious pneumonia and bone weakness in older women.

275. In accord with these findings, every version of the Advair label since Advair 250/50's limited COPD/bronchitis approval in April 2003 has included language reflecting that Advair 500/50 is *not* indicated for COPD for safety and efficacy reasons.

276. Despite the Advair labeling and GSK's own clinical trial data, GSK has marketed Advair 500/50 off-label for COPD since 1999, which predates the drug's FDA-approval for asthma.

277. Relator Hamrick recalls that even after the November 2003 limited COPD approval for the Advair 250/50 dose, sales representatives were instructed to market Advair 500/50 almost exclusively. Accordingly, the Advair COPD marketing materials in use after November 2003 intentionally downplayed or otherwise obscured the FDA-approved 250/50 dose.

278. GSK continued its off-label marketing of Advair 250/50 for COPD and its exacerbations after the April 2003 COPD/bronchitis approval.

279. GSK crafted its Advair marketing and promotional campaign in an intentionally overbroad manner to cause off-label prescriptions of Advair 250/50 to be written off-label for COPD associated with emphysema and for COPD exacerbations. This scheme continued for 5 years, until the FDA broadened the Advair 250/50 COPD approval in April 2008.

280. Beginning in May 2001, and continuing during the time GSK's supplemental drug application seeking the approval of Advair 250/50 for COPD associated with bronchitis was pending, GSK trained its respiratory therapy sales representatives in the promotion of the drug to health care providers for COPD.

281. For example, Relator Hamrick, just like the entire Advair sales force, routinely engaged in role playing exercises to hone their off-label marketing skills in promoting Advair, *inter alia*, mild asthma and COPD. On November 16, 2001, Relator Hamrick's role playing acumen was evaluated by his sales manager, Barbara Curtin, at her home.

282. Ms. Curtin assessed Relator Hamrick on his role playing session and recorded the results on a formal GSK evaluation form signed and dated by both Hamrick and Curtin. Under "strengths" for Relator Hamrick's COPD role playing exercise, Curtin remarked, "Used patient profile - Laura would have been a better choice. Made points of convenience, 12 hour relief, less albuterol use**. Uncovered that she did not know the (sic) Serevent was approved for COPD**." *7AC 0000131* (emphasis added).

283. In reality, Relator Hamrick detailed *Advair* for COPD during this exercise, not Serevent. It was part of the GSK culture for management to endorse, but cover up, off-label promotion, particularly for Advair and COPD. Relator Hamrick and Curtin specifically discussed her swapping of Serevent for Advair after Curtin filled out the paperwork.

284. In accord with GSK's extensive off-label COPD training, GSK sales representatives nationwide successfully marketed Advair 250/50 and 500/50 for COPD, a fact corroborated by GSK call notes described *infra*.

285. GSK's off-label Advair COPD training gained momentum in early 2002, at which time GSK began a massive nationwide training program for its respiratory sales force that taught its sales reps how to market Advair for COPD. Blair Hamrick, along with other Advair sales representatives, received updates throughout the year on new training courses. In turn, Blair Hamrick, and all Advair sales representatives nationwide, were tested on their knowledge of the

use of Advair 500/50 for COPD. Sales representatives who did not achieve a satisfactory score on these tests were subject to discharge.

286. In the training manual GSK distributed to its respiratory sales representatives nationwide, called the Respiratory Selling Resource, emphasis is placed on medical signs and symptoms and treatment with GSK products, including myriad examples of potential questions which doctors may ask the representative, and ending always with statement: "Closings: give dosing and ask for business."

287. Although each page of the manual had printed on the bottom "For Training Purposes Only - Not to be Used in Detailing," sales representatives were responsible for knowing the manual by rote and to utilize GSK's suggested off-label sales tactics in their detailing of physicians. The manual contained examples of long complicated questions (by the doctor) and suggested answers (by sales representatives). Also included was a rather lengthy training section on "bridging statements" with a section for notes on "Advair to COPD...Just as asthma is undertreated and under recognized, so is COPD" (page 15 of the 28 page manual "Respiratory Selling Resource"). *7AC 0000106*. The manual and the training sessions that respiratory sales representatives such as Blair Hamrick attended, were intended to permit the sales representative to attend a detailing with a physician on the subject of the use of Advair in the treatment of asthma, the approved indication, then to transition seamlessly to the use of Advair for COPD, the unapproved use, then to end the session by specifically asking the physician for 'business.' These sales tactics caused physician to prescribe large volumes of Advair 500/50 for COPD for patients who were beneficiaries of government-funded healthcare programs.

288. GSK's sales training materials also educated respiratory sales reps about how to induce physicians to ask questions about the use of Advair off-label for treatment of COPD, thereby "permitting" the representative to discuss with the physician the availability of a COPD-specific "Faxback" document (Faxback #428) to support with "scientific" data the efficacy of Advair off-label for COPD. *7AC 0000067; 7AC 0000137-138; 7AC 0000149-150*

289. For example, a GSK document entitled "COPD Market Development Selling Resource/Semester II - 2002" came with a designated "Faxback" document that the physician was supposed to request. *7AC 0000132-0000150.* The COPD Selling Resource directed the sales representative to tell the physician that s/he does have data (specifically the Isolde and Tristan GSK-funded studies described in the designated FaxBack) on efficacy of Advair in the treatment of COPD but, to remind the doctor that the particular use is *"as of now"* not approved. *7AC 0000137* (emphasis added) No instructions or information relating to any balanced presentation of medical data was included.

290. Indeed, GSK produced several Faxbacks on the subject of Advair's efficacy in COPD in both the 500/50 and 250/50 doses. They included Faxback #428: "Advair for COPD" and another Faxback, number unknown, titled "Advair Diskus: COPD Clinical Trials." *7AC 0000150; 7AC 0000151-0000167.*

291. Notably, GSK's drug Serevent had been FDA-approved *since 1997* for use in the long term maintenance treatment of bronchospasm associated with COPD (including emphysema and bronchitis). Yet GSK's COPD marketing and training materials after the Advair came on the market in 2000 either deemphasize Serevent or omit it completely. For example, the Semester II COPD Selling Resource is equally devoted to Serevent and Advair and ICSs. The training

manual is even titled generically as a COPD selling resource so as not to imply COPD marketing should be limited to Serevent. *7AC 0000132-0000150.*

292. GSK purposefully used Serevent's COPD indication as a means to promote Advair off-label for COPD aggressively. This is evidenced by the striking lack of Serevent product mention in the COPD training and promotional materials described herein. Indeed, the significant use of "unbranded" sales pieces in COPD is inconsistent with the promotional materials for GSK's other drugs at issue this in complaint.

293. The COPD Selling Resource Manual also contained statements indicating that Advair 500/50 was safe and effective for treatment of COPD. Sales representatives were given samples of Advair 500/50 during this time period to "get the business," i.e., turn their Advair COPD marketing into Advair 500/50 use for the treatment of COPD.

294. Another example of the extensive training GSK gave its sales representatives on Advair for COPD long before the limited Advair 250/50 approval is the November 11, 2002 Memo from Steve Hnatek, COPD Product trainer, to all Respiratory PSRs, TS, MDMs, RVPs and Sales VP with the subject line New COPD Learning Systems. *7AC 0000168-0000171.* It provides:

> Hey Team:
>
> Something new is in the AIR! The time for COPD training is here. refresher courses, which include COPD Disease State and Treatment Options, and, at a later date, data on the use of ADVAIR DISKUS have been designed just for you. By completing these courses you will: 1) Be up to speed and confident in your role as a resource to your customers; 2) receive credit for completing courses under GSK's
>
> new Advanced Training Curriculum, and; 3) Be prepared for upcoming promotional efforts.
>
> * * *

> The Learning Systems will consist of three Disease State courses:
>
> Course 1: Defining COPD
>
> Course 2: COPD Pathogenesis and Pathophysiology
>
> Course 3: COPD Pharmacologic and Non-Pharmacologic Management
>
> Each of these courses is approximately 20 minutes in length and all three are currently available for completion on eForce
>
> These courses will be followed by **additional courses** on **Clinical Rational for Treatment of COPD with ADVAIR DISKUS** (available in December), which will also be approximately 20 minutes in length.

7AC 0000168-0000169 (emphasis in original).

295. Training about Advair 500/50 for COPD was a prominent part of these improper off-label training materials.

296. It was "MANDATORY" for sales representatives to complete all of these courses by the end of 2002. *Id.* (capitalization in original). GSK gave the Respiratory sales force a respite from testing on these new Advair COPD training materials "because everyone completed and was assessed on **similar learnings at some point during this past year**." *Id.* (emphasis added).

297. The third manual referred to in this Memo became available on December 6, 2002. *7AC 0000172-0000173.* On that date, Relator Hamrick and all Respiratory PSRs, TSRs, RTs, DSMs, MDMs and RVPs received an email from Jim Baughman "on behalf of Advair COPD Training." The subject of the email stated: "Action required! new COPD Learning Systems." Attached to the email was the file "Advair COPD Training.doc." *Id.*

298. Because of the lack of a COPD indication for Advair, particularly Advair 500/50, one way GSK sought to promote Advair off-label for this use during sales calls was by using

advertising materials that emphasized the similarities between the symptoms of Asthma and COPD. The goal in so doing was to induce physician targets to infer that if COPD and Asthma share common symptoms, then GSK's blockbuster asthma medicine would be effective in the treatment of COPD. This was particularly effective after May 2001, when it was publicly known that GSK had submitted its supplemental new drug application seeking FDA approval of Advair 250/50 for COPD associated with bronchitis. *7AC 0000137.*

299. In fact, the first page of the "Serevent" Selling Resource Semester I - 2002 (Semester I equates to the time period January through April) essentially admits this was GSK's Advair/COPD marketing strategy for 2002:

> **2002 COPD Strategy**
>
> We expect FDA approval for Advair for COPD in early March [the approval actually happened one and a half years later]. As a result, we will have a two-part strategy that encompasses the pre-approval and post-approval timeframes.
>
> **1. Prior to ADVAIR Approval**
>
> - **Establish the overlap between COPD and asthma**
>
> - Use the GOLD Guidelines to discuss components of COPD, including inflammation, structural changes and airway obstruction
>
> - Use the Gold Guidelines to establish the benefits of long-acting bronchodilators for COPD
>
> **2. After ADVAIR approval**
>
> - Establish COPD indication for ADVAIR
>
> - Focus COPD promotional efforts on ADVAIR
>
> *** * ***
>
> **YOUR OBJECTIVES**
>
> 1. Execute COPD strategy to meet sales goals both prior and after ADVAIR

> COPD launch.
>
> 2. Implement pre-ADVAIR promotional strategy by focusing on the core message
>
> 3. Prepare for a successful ADVAIR for COPD launch by completing the ADVAIR COPD Learning System.

7AC 0000175.

300. GSK created advertising materials carried by GSK respiratory reps that were intended to put this training into action. Specifically, they were designed to open a dialogue with physicians about COPD and the use of corticosteroids along with beta agonists (which in combination is the drug Advair) by discussing the relationship of asthma and COPD and leading to the treatment of inflammation in COPD.

301. GSK's Disease Awareness Sales Aid titled "COPD and Asthma: DIFFERENT diseases with SIMILAR symptoms" is one example of a GSK advertising piece that encapsulates the strategy to establish an overlap between COPD and Asthma. *7AC 0000190-0000193.* This was a core sales aid in use in 2002.

302. Training materials accompanied the sales aid to explain the messages planted therein. *7AC 0000194-0000197.* GSK's explanations made clear that GSK intended for sales representatives to use the sales aid to establish a connection between the treatment of COPD and the treatment of Asthma:

> The first page of the sales aid aims to show that although asthma and COPD are different diseases, there is an overlap because both disease share similar symptoms.
>
> * * *
>
> This overlap can lead to confusion, because patients with either disease may experience the same symptoms

7AC 0000194.

303. Page 2 of the sales aids discusses the significant "underdiagnosis" of COPD. GSK explains that this "underdiagnosis could result from a number of factors, including patients who don't seek treatment, physicians' limited access to or use of standard spirometry **and the difficulty of differentiating COPD from asthma**." *7AC 0000195* (emphasis added).

304. It is also telling that although this is the core COPD sales aid to be used during coveted sales calls with physicians, it fails to make even a single reference to the one drug in GSK's portfolio indicated for COPD - Serevent. GSK does not mention Serevent because GSK intended to market Advair as its COPD drug, particularly the 500/50 dose.

305. Moreover, the COPD Manual described above provided suggested language for sales representatives to use to introduce the Disease State Sales Aid:

> **OPENINGS**
>
> **Disease State Awareness Aid**
>
> Doctor, as you may know asthma is a complex disease of two main components (inflammation and bronchoconstrictions). I would like to discuss another complex disease, COPD, which may include inflammation, bronchoconstriction and structural changes.
>
> OR
>
> Doctor, as you know, it is often difficult to differentiate between asthma and COPD.

7AC 0000134;0000135.

306. Even when GSK became aware that the FDA's approval of Advair 250/50 for COPD associated with bronchitis was imminent, GSK did not throttle back its off label COPD marketing campaign for Advair 250/50 or Advair 500/50. GSK "pre launch" Advair 250/50 COPD training materials evidence GSK's intent to continue to market Advair 500/50 off-label

for COPD and to continue marketing Advair 250/50 beyond the limited COPD associated with bronchitis approval. For example, on October 21, 2003, GSK circulated a memo announcing the Advair COPD prelaunch training describes information about forthcoming training manuals and required eForce testing for Advair sales representatives. *7AC 0000200-0000201*.

307. GSK intentionally fails to differentiate between Advair 250/50 and 500/50 throughout the Memo. GSK also fails to limit the training materials to the COPD/bronchitis approval. For example, the three COPD training manuals are titled as follows:

- Manual 1 - COPD Background and Overview
- Manual 2 - Clinical rationale for Treatment of COPD with ADVAIR DISKUS
- Manual 3 - Selling ADVAIR DISKUS IN COPD

Id.

308. As GSK intended, Advair sales representatives understood GSK's extensive COPD/Advair training to be a directive to promote Advair off-label for COPD during sales calls.

309. For example, on May 5, 2002, GSK detailed Dr. Harold Nelson of National Jewish Hospital on the use of Advair in COPD and the safety of Serevent, the long lasting beta agonist component of Advair, including a discussion of data on the use of Advair for COPD. In that meeting Dr. Nelson indicated that he was involved in the study GSK was sponsoring on users of Serevent who suffered adverse consequences, including those who had to be intubated, as well as fatalities among 35,000 Serevent users, a study which GSK subsequently discontinued. However, Dr. Nelson, who has been utilized by GSK to defend Advair in response to critical journal articles, and who is supposed to be a "thought leader" and leading researcher, stated in a call note on May 28, 2002 that he "wants some data on Advair for COPD."

310. The following are additional representative examples of GSK contact reports that evidence off-label promotion of Advair for COPD, particularly Advair 500/50:

- On *2/26/02*, a GSK sales rep met with Dr. Steven Weiss of Denver, Colorado. Advair Diskus was the primary drug detailed by the rep. The doctor discussed his off-label use of Advair for COPD. Dr. Weiss also indicated he liked the COPD exacerbation data detailed during that call. The sales rep gave the physician multiple samples, including 7 samples of Advair 500/50 and 10 samples of 250/50, undoubtedly for COPD patients.

- On *February 11, 2002*, a GSK sales representative called on Dr. James Ellis of Denver Colorado. According to the detailing notes, Dr. Ellis "likes Advair for tx of copd." during a *May 22, 2002* follow up call, Dr. Ellis reiterated that "he feels his copd patients benefit from it." "It" refers to Advair, as that was the only drug detailed during the May 22, 2002 call. The sales rep provided Dr. Ellis with 10 samples each of Advair 500/50 and 250/50. The sales rep detailed Dr. Ellis again on *3/21/02*. The only product detailed was Advair Diskus. According to the call note, the sales rep promoted Advair off-label for COPD: "discussed the use of ICS inb [i.e. Advair Diskus] regards to prevednting re admission to a hospital and overall mortality. Believres the data anbd his a big promponent of ics in both asthma and copd." (misspellings in original). The rep provided the doctor with 7 samples of Advair 250/50 and 10 samples of 500/50.

- On *4/12/02*, a GSK sales rep promoted Advair for COPD to Dr. William Pluss of Denver, Colorado: "committed to 1 king prog, think of ics in asthma and copd." (misspelling in original). The only drug detailed during this COPD detailing was Advair.

- On *5/22/02*, a GSK sales rep detailed Dr. James Sllis of Denver, Colorado exclusively on Advair Diskus. According to the detailing notes, COPD was promoted: "ptom (sic) control he said he feels his copd patients benefit from it." The doctor was given 10 samples each of Advair 500/50 and Advair 250/50.

- On *July 3, 2002*, a GSK sales rep detailed Dr. Nina Sweeney of Roanoke, Virginia. Advair and Flonase were the sole drugs detailed. According to the call note, "Asked for 500/50 for indigent patient. Told her about our programs and still asked. Using a lot of Advair said she switched a patient who was on Pulmicort and Serevent to Advair. * * * She then told me she sees more COPD than asthma and asked for information. Sending her faxbk 428." Faxback 428 provides is a thinly-veiled marketing piece for Advair 500/50 off-label use for COPD. On *July 24, 2002*, the sales rep paid a follow up visit to Dr. Sweeney. Advair and Flonase were detailed. According to the call note, "Said she is using more Advair went over the Fxbk and benefit to patient with COPD." Accordingly, these call notes constitute direct evidence of off-label promotion of Advair 500/50 for COPD.

- On September 30, 2002, GSK sales rep Peter Copeland detailed Dr. Daniel Citron of Denver, Colorado. According to the call note, "Advair core message COPD market development, he is really positive about Advair."

- On January 15, 2003, a GSK sales rep detailed Dr. Nathaniel Moore. Advair and Flonase were sampled. According to the call note, "called for Advair samples - copd cme invitation." The sales rep left 4 samples each of Advair 250/50 and 500/50.

7AC 0000202-0000210.

1. GSK's Improper Use of Speakers and National Thought Leaders to Promote the Off-Label Use of Advair for COPD

311. GSK employed Sydney S. Braman, M.D. from Brown University School of Medicine to promote the use of Advair 500/50 in the treatment of COPD by paying Dr. Braman, who had been a consultant to GSK and a member of GSK's "Speakers Bureau," to present multiple CME programs that advocated the use of spirometry in the differential diagnosis of COPD and asthma. GSK sponsored these programs through education grants, however to create a false perception that these programs were independent from GSK, they were officially hosted by an agency known as Intellyst Medical Communications.

312. On November 27, 2002, GSK distributed to each of its respiratory sales representatives nationwide information concerning an Interactive Voice Response (IVR) presentation by Dr. Braman available to participate in via teleconference from December 2, 2002 through February 28, 2003. *7AC 0000211-0000212.* The CME was "sponsored through an educational grant" from GSK.

313. According to the GSK memo, "the program will provide information on the management of and treatment options for COPD, including acute exacerbations and stable COPD, as well as similar or co-morbid disease states since the management of these conditions can be different." *Id.* In other words, the object of the telemarketing program was to discuss

available prescription options for treating COPD and to discuss asthma and COPD to highlight the similarities of these conditions.

314. Each representative received 50 printed invitations for physicians and 50 invitations for pharmacists. *Id.* In keeping with GSK's method of publishing express disclaimers on all official documents from the company, the memorandum included an admonition that the material was not to be used for the promotion of Advair for COPD and that questions were to be forwarded directly to Dr. Braman. *Id.* Contrary to GSK's admonition, however, GSK designed and intended the program to be used by sales representatives to promote Advair for the treatment of COPD. This was an aggressive marketing ploy as Advair 250/50 had not even received its limited COPD approval at that time.

315. The program was available to health care professionals on a 24/7 basis, and the healthcare professional could receive CE or CME credit after listening to the ½ hour to 1 hour program by answering five questions posed at the end of the recorded presentation.

316. In this nationwide telemarketing program, Dr. Braman utilized GSK's two primary Advair 500/50 COPD clinical trials - Isolde and Tristan - to persuade physicians that Advair 500/50 was safe and effective for COPD. Both studies were limited to testing Advair 500/50 for the treatment of COPD. Advair 250/50 was not included in the studies. GSK used the Tristan and Isolde study as key marketing tools in the off-label promotion of Advair 500/50 for COPD.

317. In this program and in its marketing generally, GSK obfuscated intentionally the Isolde trial results that confirmed Advair 500/50 increased the risk of respiratory infections and pneumonia when used to treat COPD patients. GSK masked similar findings made in the Tristan trial, which was a larger trial conducted as a follow-up to the Isolde trial. Specifically, the Tristan

trial demonstrated an increased number of lower respiratory infections and pneumonia in the Advair treated group v. placebo.

318. The Tristan Study was the subject of a Lit Alert dated February 2003. At the time, the Tristan study was "the largest and longest Advair Diskus study for COPD." *7AC 0000213-0000214.*

319. On the Lit Alert cover page, the following are the "KEY MESSAGES" GSK instructed should be taken away from the Study:

KEY MESSAGES:

a. In patients with COPD, Advair Diskus 500/50 BID significantly:

i. improved lung function (FEV1 and other lung measures)

ii. reduced exacerbations (that required oral corticosteriods or antibiotics)

iii. improved symptoms (breathlessness)

iv. reduced the use of rescue albuterol

v. improved health status

Id.

320. GSK described the study "Conclusions" in the Lit Alert as follows: "The authors concluded that treatment with Advair produced better control of symptoms of lung function with no greater risk of adverse events than those with either FP or salmeterol alone. Therefore, Advair Diskus is an effective treatment option for many patients with COPD."

321. GSK's conclusion materially minimizes and obscures the significant and even life threatening side effects of Advair 500/50 identified in this study.

322. Data from the Tristan Study, along with two other studies, were the subject of promotional Faxback #428.

323. GSK's designation of "KEY MESSAGES" and making this off-label Advair Diskus 500/50 study the subject of a Lit Alert and Faxback #428 directly contradicts the admonition printed on the bottom of the page that ,"This material is for your information only. This information should not, under any circumstances, be carried by sales representatives or utilized in any manner for product detailing."

324. Indeed, it makes virtually no sense that the GSK Medical Information Department would go to such great lengths to prepare, publish and disseminate to all sales representatives a Lit Alert on the Tristan Study if they were expected to completely disregard the KEY MESSAGES in sales calls.

325. Moreover, at the time GSK published this Lit Alert and Faxback #428, GSK knew the FDA's *approvable* letter for Advair Diskus was limited to 250/50 only, and in that dose only for COPD associated with Chronic Bronchitis.

326. The Isolde and Tristan studies were incorporated into other off-label non-CME speaker programs that promoted Advair 500/50 for COPD even before Advair 250/50 even had a COPD indication.

327. On April 8, 2003, Relator Blair Hamrick organized a catered evening speaker program at Critical Care & Pulmonary Consultants, PC for top tier speaker Dr. Ron Balkissoon of National Jewish Medical & Research Center titled, "Optimizing Care of the COPD Patient: Current and Future Directions." *7AC 0000215-0000222.*

328. Relator Hamrick was directed to characterize the program as an asthma program in soliciting his physician-clients to attend, when in it fact it was clear the program would promote for Advair for COPD, in particular Advair 500/50.

329. Relator Hamrick was resistant to organizing his program because it was so plainly off-label, as at that time Advair 250/50 did not even have a CODP/bronchitis indication. However, he was required to organize it by Ned Schneidewind.

330. The slides from that presentation are incorporated herein by reference

331. The first few slides compare asthma and COPD, to set up the slides which promote Advair, an asthma medication, for COPD. The transition slide discusses how COPD patients could benefit from ICSs. The slideshow then goes into "The Evidence." The "evidentiary" slides are derived from explicit references to the off-label Isolde and Tristan studies which involved the study of Advair 500/50 for COPD. The slideshow even goes so far as to explicitly reference Advair by its chemical name, Fluticasone/Salmeterol, in conjunction with COPD in introducing the data on the Tristan Trial.

332. Thirty eight physicians from Critical Care & Pulmonary Consultants, PC attended this promotional program. *7AC 0000223.*

333. This is a perfect example of the off-label manner in which GSK marketed Advair 500/50 off-label for COPD when no dose of Advair had yet been approved for any use in COPD.

334. GSK's Thought Leaders and speakers were also used to publish journal articles that advocated the use of Advair 500/50 for COPD. This was yet another way GSK sought to create, by appearances only, "independent" peer reviewed support for this off-label use in respected medical authoritative sources. For example, GSK utilized medical authors Dr. P. Calverley (Tristan trial) and Dr. P.S. Burge (Isolde trial) to write journal articles utilized in the selling Advair 500/50 for COPD. Burge's Isolde article (BMJ 2000) affirmatively misrepresented the adverse side effects of the drug; the article failed to even mention pneumonia.

335. The Tristan article by Calverley (Lancet 2003) also failed to disclose the increased risks of pneumonia and respiratory infections. Burge's Isolde distorted presentation was incorporated into a PowerPoint used nationwide that was put together by Dr. Braman.

336. As part of the pre-indication marketing drive, GSK rewarded 'thought leader' physicians who helped in the process of getting the word out on the use of Advair for the treatment of COPD. At the regional meeting of respiratory therapists in Las Vegas, Nevada in September of 2003, sales manager Jim Heinl told Blair Hamrick, along with the entire sales district, that he had "just personally handed Dr. Broughton a very large check [a grant check for $25,000.00] last week, because he is on the COPD advisory committee, so he is in our camp."

337. GSK also paid large sums to physicians from National Jewish Hospital in Denver, Colorado, including Dr. Barry Make, Dr. Hal Nelson and Dr. Jack Routes, to present lectures nationwide (and internationally) on the efficacy of "combination therapy" (Advair) for the treatment of COPD prior to its approval by the FDA.

338. GSK co-sponsored presentations by doctors at the national meeting of the American College of Chest Physicians Nov. 2-7, 2002 in San Diego, California, where physicians lectured on the issue of the use of corticosteroids in the treatment of COPD. In the months following the conference, Relator Hamrick was asked to arrange a "peer-to-peer" lunch conference on the subject of corticosteroids for the treatment of COPD, a thinly veiled reference to the use of Advair, which was the only combination corticosteroid/beta agonist product on the market.

339. GSK Respiratory Therapeutic Specialist Patrice Proestas recruited Dr. Ron Balkissoon from National Jewish Hospital to perform this 'peer to peer' speaking engagement in Denver. Dr. Balkissoon was paid by GSK to give the presentation, using GSK-authored

PowerPoint materials but re-labeling them as his own, on April 8, 2003. His presentation was essentially the same as Dr. Braman's and utilized the misrepresentations in the Burge and Calverley articles that touted Advair 500/50 as effective and safe for the treatment of COPD.

340. On information and belief, Dr. Balkissoon continues to reap the benefits of speaking for GSK and, as recently as the second quarter of 2009 alone, he received $3000 as a consultant and an additional $27,000 in speaker fees.

2. GSK's Use of Faxbacks and Journal Articles in the Off-Label Marketing of Advair for COPD

341. During and after the pre-approval period of Advair for COPD, GSK utilized Faxback 428, which incorporated the Berge and Calverley articles, to sell Advair 500/50 for COPD. Additionally, the 2002 Respiratory Selling Resource incorporated the Faxback information and articles and specifically alluded to Advair 500/50's efficacy and safety for COPD. Such representations were contrary to the label for Advair 500/50, which includes the statement: "Higher doses [of Advair], including ADVAIR DISKUS 500/50, are not recommended, as no additional improvement in lung function (defined by predose and postdose FEV1) was observed in clinical trials and higher doses of corticosteroids increase the risk of systemic effects."

342. GSK's publication of the TORCH study, a clinical trial of Advair 500/50 for COPD begun in 2004, was designed to tout the effectiveness of Advair 500/50 for COPD, and the February 22, 2007 New England Journal of Medicine article was touted to GSK's investors in a 2007 PowerPoint presentation by Stan Hull as supporting the supplemental new drug application for COPD.

343. However, on August 9, 2007, the FDA denied the Advair 500/50 COPD indication, stating that the TORCH study failed to show that it improved the survival rate and that there was a significant increased risk of pneumonia.

344. GSK's illegal, off-label selling of Advair 500/50 for COPD and its misleading characterization of the side effects found in the Tristan and Isolde studies has endangered patients, as demonstrated in studies by P. Ernst *et al.* "Inhaled Corticosteroid Use in COPD and the Risk of Hospitalization for Pneumonia," (AJ RespCrit, March of 2007) and by S. Singh *et al.*, "Long-term Use of Inhaled Corticosteroids and the Risk of Pneumonia in COPD" (JAMA, Feb. 2009). Specifically, among other things, GSK failed to disclose the serious risk of pneumonia caused by Advair 500/50 when used to treat COPD.

3. GSK Routinely Violated the Anti-Kickback Statute in its Marketing Activities for Advair

345. In addition to off-label promotion of Advair for mild asthma and Advair 500/50 for COPD, GSK provided doctors nationwide with free COPD and asthma diagnosis equipment. The diagnostic equipment constituted a kickback because the in kind gift was intended to induce those physicians to prescribe Advair in exchange.

346. Specifically, beginning in the Fall of 2001, GSK began gifting free spirometry devices to physicians who treat COPD and asthma. This program was known as "Project Spirometry." *7AC 0000224.*

347. Spirometry is a basic measurement of the patient's ability to move air into and out of his or her lungs. In particular, office-based screening spirometry focuses on how much air a person can forcibly exhale, for example, in one second (forced expiratory volume, FEV1) compared with how much air he or she can exhale after a maximum inhalation (forced vital capacity, FVC). The ratio of these 2 values is also calculated (specifically FEV1/FVC).

Spirometric values are measured with a spirometer, essentially a tube with a mouthpiece attached to a measuring device (usually a microcomputer). A patient blows into the tube, and the spirometer measures and displays the results in both graphic and numeric form.

348. It is also notable that at this time, Advair 250/50 had not yet been approved for COPD associated with bronchitis.

349. Along with the spirometry devices, GSK representatives provided physicians with the appropriate CPT codes for billing Medicaid and Medicare for testing patients with the devices in violation of the Anti-Kickback Statute.

350. Sales representatives also instructed the physicians on how to most effectively use the spirometry device. In fact, GSK devoted substantial resources to training its sales representatives on the use of spirometers. In fact, GSK sponsored a "Masters of Spirometry" training program, which all Advair sales representatives, including Relator Hamrick, were required to complete. *7AC 0000225-0000272.*

351. At GSK's instruction, sales representatives told physicians to do an initial pulmonary function test, wait five minutes, administer a fast-acting beta agonist such as Albuterol, repeat the test and, if no change in function, then the diagnosis would likely be COPD. At that point the subject of Advair for the treatment of COPD would be brought up.

352. Sales representatives were told not to accentuate that Spirometry, in the absence of prior clinical symptoms, has been determined to be of little value in the diagnosis of COPD. Instead, as instructed in the 40 Page GSK "Masters of Spirometry" training manual, they were told to promote that spirometry:

> can detect the presence of airways obstruction, as seen in COPD (eg, emphysema) before there are any symptoms of the disease. Since advanced COPD has a significant mortality rate, early detection may mean earlier treatment recommendations, and hence lower rates of disability and death. Many studies

> and clinical practice guidelines recommend that clinicians use spirometry to screen all patients over age 45 who smoke.

7AC 0000270.

353. GSK actively monitored the number of Advair prescriptions written by physicians given spirometry devices to track GSK's return on its investment in this kickback scheme.

354. The following are examples of some of the physicians in the State of Colorado to whom GSK gave spirometers and thereafter tracked their prescription trends: Dr. Odekirk, Dr. Colander, Dr. Scott and Dr. Lewis.

355. Although GSK made its sales representatives sign a document promising that the spirometers were 'loaned' and that they would collect the spirometers from the physicians and clinics that were provided with them, there was no program to account for the thousands of spirometers distributed nationwide.

356. GSK's intent in giving away the free spirometers to physicians was to get them to prescribe Advair in return.

VIII. GSK'S OFF-LABEL MARKETING OF AMERGE AND IMITREX

357. Imitrex (Sumatriptan Succinate) and Amerge (Naratriptan Hydrochloride) are GSK's principal prescription medications for the treatment of migraine headaches. They are known as "triptans." Triptans stimulate serotonin (a chemical needed to transmit various nerve signals to the brain), decrease inflammation, and reverse blood vessel dilation (expansion) around the brain, thereby relieving the migraine or cluster headache symptoms.

358. There are three FDA-approved forms of Imitrex. Imitrex Injection received its initial approval by the FDA in 1993, followed by approval in tablet form in 1995 and in nasal spray form in 1997. Imitrex Injection, Tablets and Nasal Spray shall hereinafter be referred to as "Imitrex " except where otherwise indicated.

359. Imitrex Tablets, Nasal Spray and Injection are FDA approved for the acute treatment of migraine attacks with or without aura in adults. Imitrex Injection has a second FDA-approved use, for the acute treatment of cluster headache episodes.

360. The FDA approved Amerge in 1998 for acute treatment of migraine headaches.

361. Generally, because the onset of action for Amerge is slower than that of Imitrex, it is erroneously perceived as more mild by many physicians and patients.

362. GSK has disregarded Imitrex's and Amerge's narrow FDA-approvals since their respective launches and instead promoted Amerge and all Imitrex formulations for a litany of off-label uses such as prophylactic treatment of migraine headaches in pregnant women, treatment of menstrually-related migraine headaches, sinus-related headaches and acute tension (non-migraine) headaches.

363. In addition, neither Amerge nor Imitrex has been FDA-approved for any use whatsoever in patients under the age of 18. In fact, the Amerge and Imitrex labels expressly warn that these drugs are have not been proven safe or effective in children.

364. The Amerge label provides:

> **Pediatric Use:** Safety and effectiveness of AMERGE tablets in pediatric patients (younger than 18 years) have not been established.

365. The cautionary language against pediatric use is even more strongly worded for Imitrex. Specifically, the Imitrex Tablet, Nasal Spray and Injection labels all instruct that:

> **Pediatric Use**: Safety and effectiveness of IMITREX [Injection, Tablet, Nasal Spray] in pediatric patients under 18 years of age have not been established; therefore IMITREX [Injection, Tablet, Nasal Spray] is not recommended for use in patients under 18 years of age.

366. As discussed *infra*, Imitrex clinical trials and post-marketing data proved that the serious and even life threatening side effects of these drugs, including stroke and myocardial infarction, *are more prevalent in the pediatric population than in adults*.

367. Indeed, the FDA rejected GSK's supplemental drug application seeking a pediatric indication for Imitrex nasal spray to treat migraine headache because of the drug's risks to this age group and the lack of scientifically proven efficacy.

368. Despite the scientific evidence that these drugs are particularly dangerous to children, GSK marketed both drugs to pediatrics, consciously jeopardizing the health and safety of this vulnerable population.

369. GSK's marketing strategies for Imitrex and Amerge proved to be successful. As then Glaxo Wellcome Chief Executive Officer Sir Richard Sykes stated in July of 2000, "[I]n the USA our marketing strategies have helped reverse the decline in our migraine treatment Imitrex/Imigram resulting in an overall growth of our migraine portfolio of 10 per cent."

370. By year end 2003, total U.S. sales of GSK's Imitrex and Amerge totaled approximately $1 billion.

A. Off-Label Promotion of Imitrex and Amerge Beyond Migraine

1. Marketing For Mild Headache

371. Similar to its off-label marketing approach with its other prescription drug products, GSK indoctrinated its sales force with information concerning the safety and efficacy of its migraine drugs for off-label uses, including for mild headache, tension headache, sinus headache and as a prophylactic for headache and migraine.

372. GSK did so in sales training seminars, its sales training materials, and marketing materials, such as detail aids and faxbacks.

373. One such GSK training seminar for TSR sales reps was held on December 5, 2000 in Las Vegas, Nevada. Relator Hamrick attended this training seminar and at that time was given a copy of slides presented during the training, which are incorporated herein by reference. *7AC 0000273-0000322.*

374. The slides cover the gamut of GSK off-label promotion for Imitrex and Amerge, including:

- Use of Imitrex for mild headache, couched in terms of Early Intervention ;
- Use of Imitrex to treat the Spectrum of Migraine Headache, including tension and migraineous headache;
- Use of Imitrex to treat Adolescent Migraine;
- Use of Amerge for Menstrual Migraine; and,
- Use of Amerge for Prophylaxis.

Id.

375. GSK attempted to disguise its mild headache campaign as "Shifting the Treatment Paradigm" to "Early Intervention" at the first sign of headache, when the pain is "still mild." *Id.*; *7AC 0000278.* The result, according to GSK, is pain free relief, which is the number one goal of migraine sufferers.

376. Imitrex and Amerge are FDA-approved to treat migraine headaches, not mild headaches or mild pain.

377. GSK termed this a "Shift the Treatment Paradigm," because at that time the migraine treatment protocol was to prescribe Imitrex for use at the onset of migraine pain (as it is labeled), whereas with the new treatment paradigm, GSK sought to convince doctors to prescribe

Imitrex at the first sign of the onset of a mild headache as essentially as a preventative for the onset of a migraine.

378. The thinly-veiled purpose behind this marketing campaign was to promote overuse of Imitrex which included off-label uses for non-migraine, and mild headaches.

379. The "Shifting the Treatment" paradigm was a core "Objective" of the December 5, 2000 TSR training in Las Vegas, Nevada. *Id.* The training included an overview of scientific data for use in convincing doctors that Early Intervention left patients pain free.

380. This efficacy data is contrived. GSK conveniently omits from the analysis that the "pain free" result of early intervention could just as easily be explained by the fact that the patient was experiencing a mild headache, not early signs of a migraine.

381. Moreover, GSK cannot explain away that the marketing is targeting treatment of mild headache and not migraine.

382. The "Imitrex Selling Resource Semester II - 2001" sales training manual GSK provided to all Imitrex sales representatives also keyed on the "Early Intervention" treatment paradigm for Imitrex. *7AC 0000323-0000341*.

383. Among other things, the Imitrex training manual recommends questions to pose to physicians during sales calls that were designed to:

- open up conversation on the subject of Early Intervention (And, "Doctor, when treating early in the mild pain phase, you can optimize efficacy. How does this affect your treatment of migraine?) *7AC 0000326;*
- to direct the conversation to a discussion of Early Intervention ("Doctor, is it fair to say that failure to use an effective migraine treatment early in the headache can result in increased pain, disability and headache impact?) *7AC 0000327*; and,

- "closing questions" calculated to "establish the intent to prescribe" Imitrex for mild headache pain ("Doctor, if you agree that the early intervention data we have discussed today will benefit your migraine patients, will you agree to counsel your patients to take their Imitrex early in the mild pain phase?")

Id.

384. GSK foresaw that physicians would resist sales reps' marketing of an expensive migraine medication for mild headaches. Therefore, GSK prepared its sales reps by providing scripted responses to anticipated physician objections. These scripted responses basically dodged the issue, because there was no valid response, and spun the facts to favor Early Intervention. For example:

- **Resistance to early intervention**
  Objection**:** If I use Imitrex early, how do I know if it is going to turn into a migraine?

  Solution - Doctor, 98% of all migraine patients report that they experience moderate to severe pain. The point being, patients need to be told to take their medication early.

  Proof Sources - Faxback Letters #4065, and #408

- **Imitrex is too Expensive to use for every migraine.**
  Objection - If I am using Imitrex early in the migraine and 98% of all headaches turn into moderate or severe headaches, am I going to use more Imitrex?

  Solution - No doctor, in fact, if you treat the migraine at the first sign of pain or when the pain is mild, you may use less drug since efficacy rates increase to 68% with 100mg tablets in 4 hours.

  Proof Source - Faxback Letter # 408

  Sales Tools - Faxback Letter #408, Pain Free Sell Sheet

7AC 0000330.

385. Notably, GSK even provided sales reps with a Faxback specifically titled "Economic Benefits of Early Intervention with Imitrex" to support this off-label marketing campaign and combat this appropriate physician objection. *7AC 0000342-0000347*.

386. Training on objection handling for Early Intervention was also covered during the December 5, 2000 TSR training in Las Vegas. *7AC 0000273-0000322.*

387. The Imitrex marketing team also created a Imitrex User's Guide for physician use. The manner in which GSK sales reps were expected to use the Imitrex User Guide to promote Imitrex off-label for mild headache is discussed in the Imitrex Selling Resource Semester II 2001:

> utilize this Guide as a tool for your physician to educate their migraine patients on their headaches and the importance of IMITREX in their treatment regimen. **While Imitrex has been shown to work anytime during a migraine attack, headache experts believe the optimal strategy for migraine is to act early, when the pain is still mild**. Unlike some generic pain relievers, IMITREX targets your patient's total migraine - the pain and associated symptoms. Also, unlike some other prescription medications that leave your patients drowsy and may be habit forming, IMITREX provides your patients non-drowsy therapy which is not habit forming.

7AC 0000339 (emphasis added).

388. Another Imitrex Sales Tool, the "Pain Free Sell Sheet," echoes the off-label sales message that early intervention with Imitrex, when the pain is still mild, gives patients pain free relief. *Id.*

2. Marketing for Sinus and Tension Headache

389. According to GSK, one of the top three migraine market issues to overcome for Imitrex in 2001 was:

- **Diagnosis**

  -52% of migraine patients remain undiagnosed

-Migraine is often misdiagnosed as sinus or tension headache

7AC 0000325.

390. This is a thinly-veiled reference to GSK's intent, as part of the marketing of Imitrex and Amerge, to convince physicians to rediagnose patients with sinus and tension headache as migraine suffers.

391. One way GSK promoted Imitrex for non-migraine headache was to promote the drug as effective in the treatment in the "range of headaches" in migraine, which GSK broadly defined to encompass migraine, migraineous and tension type headache.

392. For example, GSK made available to GSK sales reps a reprint summarizing the Spectrum Study tiled: "The Range of Headaches in Migraine sufferers: Results of Spectrum Study." The Spectrum study was pivotal to the marketing of Imitrex for non-migraine headache. The Spectrum Study was funded by GSK and authored in principal part by Dr. Cady, who had substantial financial ties to GSK, as is alleged in detail in subsection “C” below.

393. Cady's study touted Imitrex's efficacy in the Spectrum of headaches suffered by migraine patients, including "migraine, migraineous and TTH [tension type headache]." 7AC0000348-0000350; 0000336.

394. GSK marked the reprint "off-label," and "for use in response to unsolicited questions" and "Not for promotional use," but this was just lip service to appear compliant with off-label marketing prohibitions. 7AC0000348-0000350.

395. Another example of how GSK attempted to pollute the scientific data on sinus versus migraine headache was the self-serving 2004 GSK-funded study titled "Prevalence of migraine in patients with a history of self reported or physician diagnosed sinus headache." This study "concluded" that "88% of patients with a history of sinus headache were determined to

have migraine type headache. The physicians credited as authors of this study were Drs. Schriber, Hutchinson, Ames, Richardson and Powers.

396. This study is another example of the manner in which science can be manipulated to serve the marketing ends of a pharmaceutical manufacturer. In the case of this study, however, Dr. Alexander Chester, a Clinical professor of Medicine, from Georgetown University Medical Center in Washington, DC published an article titled "The Demise of Sinus Headache is Premature" in the Archives of Internal Medicine exposing the engineered conclusions of the Schreiber et al study. *7AC 0000351-352***.**

397. Specifically, Dr. Chester opined that the Schrieber et al study result conclusion was:

> largely based on the definition the authors selected: The International Headache Society rejects chronic sinusitis, but not acute sinusitis, as a cause of headache. Because patients with acute sinusitis were excluded from the study of Schreiber et al study, by definition, any patient with a headache could not have had a sinus headache. Therefore the authors' conclusion that another source caused the headache was inevitable.

Id.

398. Dr. Chester also posited that "much of the phenomena that Schrieber et al describe in their study sponsored by GlaxoSmithKline could be better viewed as vascular symptoms of chronic sinusitis rather than nasal symptoms of migraine. *** ... in any case, more proof is needed before alleging that 88% of sinus headaches are misdiagnosed." *Id.*

399. In mid 2003 and 2004, GSK launched a new strategy to promote Imitrex for sinus headache. The strategy involved the co-promotion of Flonase with Imitrex in CME and other speaker programs. GSK chose Flonase because of its FDA-approval to treat Allergic Rhinitis, which is a condition of the sinus, thus packaging the drugs together created a perfect segue to marketing Imitrex for sinus headache.

400. As part of this scheme, GSK sponsored CME programs that combine lectures about Allergic Rhinitis and "Migraine." For example, GSK sponsored a *complementary* 4 credit CME on July 12, 2003 at the Omni Interlocken resort in Bloomfield CO, called *Understanding Migraine and Perennial Rhinitis*. Not coincidentally, both program speakers - Judy Lane and Joe Spahn - have substantial financial ties to GSK. *7AC 0000353-0000354***.**

401. Indeed, Judy Lane, who spoke on the topic of migraine, gave multiple promotional Imitrex lectures on the benefits of the drug for pediatrics. As discussed infra, Judy Lane is referenced in contact reports as well as in the speaker section.

402. The CME marketing materials reveal that GSK's purpose in sponsoring this program was to disseminate the message that sinus and tension headaches are in fact misdiagnosed migraine headaches, but in a peer-to peer CME format that gives what, in truth, is a promotional message, the veneer of independence. *Id.*

403. Indeed, the following is the Statement of Purpose quoted from the CME brochure:

> Recurrent undifferentiated headaches are frequently thought to be caused by sinus congestion or tension when in fact they are more commonly migraine variants. New data has shown that the symptoms that led to incorrect diagnosis are due to referred pain, and that these headaches can be successfully managed by newer classes of migraine therapy. This new understanding of the pathophysiology of headache has revolutionized the old paradigms of headache care.
>
> * * *
>
> This CME activity will provide primary care physicians with the newest information on the management of migraine and perennial rhinitis.

Id.

404. The program's speakers - Judy Lane and Joe Spahn of National Jewish Hospital - were both GSK-paid national speakers known to Relator Blair Hamrick.

405. Notably, the program materials do not mention Imitrex, because product promotion identification is prohibited in CME materials. Nevertheless, it was Relator Hamrick's understanding that Imitrex was promoted by the speaker during these co-promotional CMEs. Indeed, that was GSK's purpose in sponsoring these CMEs and selecting speakers with significant GSK financial. *Id.*

3. Off-Label Promotion for Menstrual Migraine, Prophylaxis and Use During Pregnancy

406. Menstrual migraine is migraine without aura that occurs in at least 2/3 of menstrual cycles during the 5 day perimenstrual period from day -2 through day =3 (day 1 = first day of flow).

407. Menstrual migraine is divided into 2 types:

- **Pure Menstrual Migraine:** migraine without aura that occurs exclusively during the 5-day perimenstrual window of -2 through =3.
- **Menstrually-Related Migraine:** migraine without aura that occurs during the 5-day perimenstrual window of -2 through =3 but occurs at other times of the cycle as well. Menstrually related migraine is much more common that Pure Menstrual Migraine.

408. GSK overtly marketed Imitrex and Amerge for both types of menstrual migraine.

409. As alleged above, GSK trained its sales reps about the safety and efficacy of Imitrex and Amerge during the December 5, 2000 Las Vegas TSR training. *7AC 0000309-0000313.* Indeed, the presentation contained a series of slides devoted to data that "supports" Imitrex and Amerge use in Menstrual Migraine. *Id.*

410. GSK supported this training with sales tools. For example, the Imitrex detail aid known as the Masquerade Detail Aid, contained data in Imitrex use for Menstrual Migraine. *7AC 0000312*. Similarly, GSK had faxbacks available that supported this off-label use for both Imitrex and Amerge. For Imitrex, GSK created Faxback #206, "Imitrex: Efficacy in Menstrual

Migraine" and "Use of Imitrex in Patients with Menstrual Migraine and Menstrually Related Migraine." *7AC 0000356-0000362; 7AC0000366.*

411. In February of 2002, GSK distributed to its sales representatives an Faxback entitled "Use of Amerge Tablets in Menstrual Migraine." *7AC 0000363-0000365*. In addition to highlighting positive study data on this off-label use of Amerge, the Faxback instructs that the International Headache Society (IHS) did not distinguish Menstrually Associated Migraine as a separate entity within the category of acute Migraine headaches without aura. This was a useful tool in attempting to blur the lines between menstrual migraine and migraine to obfuscate Amerge's lack of FDA-approval for this use.

412. While Faxbacks ostensibly were to be used in response to unsolicited off-label questions, in reality, they were intended for active use as part of GSK's off-label Amerge and Imitrex off-label promotional scheme.

413. As an extension of the menstrual migraine marketing campaign, GSK also promoted Amerge for *Prophylaxis* for Menstrually-Related Migraine.

414. Amerge is not FDA-approved for Prophylaxis therapy for migraine or otherwise. Nevertheless, GSK promoted the drug as safe and effective to use a few days before a woman's period was expected to begin and continuing for a total of six days to prevent the onset of menstrual migraine.

415. Prophylactic use involved a 6 day dosing regimen every month, but without regard for whether the patient would even suffer a headache, much less a migraine.

416. GSK supported the Amerge prophylactic marketing campaign with the GSK-funded Amerge Prophylaxis Study (S2WA4006). *7AC 0000313.* GSK used this study as a promotional tool to claim Amerge was efficacious when used 3 days before the expected onset of

menses and continuing for 6 days to prevent a menstrually-related migraine from occurring. This study was the topic of Amerge Faxback #500.

417. GSK also promoted Amerge for Prophylactic use for Daily Headache or Transformed Migraine.

418. GSK combined promotion of these off-label uses in the Faxback titled "Prophylactic Use of Amerge Tablets," i.e., Faxback 605. *7AC 0000367-0000369.*

419. GSK also promoted Imitrex and Amerge to OB/GYNs as safe for use during pregnancy as Pregnancy Category C drugs, including through the use of off-label Faxbacks. *7AC 0000370-0000378.* Category C drugs are those which have not been studied in humans, but that appear to cause harm to the fetus in animal studies.

420. GSK's marketing contravened the Amerge prescribing information, which states that there are not adequate and well-controlled studies in pregnant women and the drug "should be taken during pregnancy only if the potential benefit justifies the potential risk to the fetus." The Amerge label further concedes that Amerge has been shown to cause birth defects and miscarriages in rats and rabbits.

421. To further this unlawful promotional campaign, both Imitrex and Amerge were heavily sampled in OBGYN offices.

B. Promotion of Imitrex and Amerge Off-Label to Children

422. GSK aggressively marketed Imitrex and Amerge for use in pediatrics. Indeed, GSK explicitly trained its sales representatives in the efficacy, long term safety and tolerability of Imitrex when prescribed to treat Adolescent Migraine, as evidenced by the December 5, 2000 TSR training slides presented by Michael Brown, Product manager. *7AC 0000309; 0000313-0000314.*

423. GSK sales reps used this instruction and directive by GSK to market Imitrex and Amerge off-label to pediatrics. The following contact reports all evidence GSK sales reps detailing these drugs off-label to pediatric specialists for pediatric use:

- On September 13, 2001, Dr. Stephen Smith, a Colorado pediatric neurologist, was detailed by GSK sales representative Ron Crews on Imitrex and Amerge. Crews took the office staff to lunch and discussed appropriate dosages of Imitrex for children with Dr. Smith and his staff. The notes indicated that "he agreed that he would use more with better technique, nasal [spray] is much better than mlts [melts]. Use more 50s and 100s and has the pts split them to get 25 mg for kids....He likes the mt [melt] for kids who won't swallow a tablet. According to nurse linda he rxs a lot of melts."

- September 24, 2001, Dr. Charon S. Nelson of Colorado Springs was again detailed by GSK sales representative Ron Crews and sampled with Imitrex and Wellbutrin SR samples with a note that indicates "asked her to consider wsr when thinking of a ssri. She agreed and took it further and painted several pt pictures. She uses 5-6 mg/kg for kids who have depression and adhd."

- May 8, 2002, Dr. Stephen Smith was detailed on Imitrex Nasal Spray and tablets. The Contact Note states: "went over t max of melts and im nasal faster and talked about quick onset and and short acting ha in adol and he agreed."

- September 12, 2002, Dr. David B. Roos of Aurora, Colorado was detailed by a GSK sales representative for Imitrex Nasal Spray and Imitrex Tablets with a note indicating: "Dr uses 25mg in kids and asked if still offered. Asked if 50's can be cut in half in cutter [indicating if the adult size dosages could be reduced by 50% utilizing a pill-splitting device]."

- September 30, 2002, Dr. Roos of Aurora was detailed by a GSK sales representative for Imitrex Tablets, Valtrex and Wellbutrin SR with a note indicating: "Follow up on prior discussion about kids and Imi [meaning Imitrex] more info on ages. Kids migs [migraine headaches] diff because they go away so fast and fast onset."

- October 21, 2002, Dr. Roos of Aurora was again detailed by a GSK sales representative for Imitrex Tablets and Valtrex with a note indicating: "Imitrex and kid studies as well as Valtrex for coldsores and new indication."

- December 6, 2002 Dr. David Roos of Aurora, Colorado was again detailed on Imitrex by a GSK sales representative with a note indicating: "Follow up on last conversation about research on kids and Imi. Speed message against melts and ac on dizzyness not good, Mom had major surgery today and he was getting a mig from stress."

- January 14, 2003, Dr. David C. Simon was detailed by a GSK sales representative on Imitrex with a note indicating: "Dr. asked me to leave samples of both 50 and 100'2 because Dr. Roos is a fan. Not indicated in children as migs are so rapidly escal."

- June 10, 2003, Dr. David Roos of Aurora was again detailed by a GSK sales representative on Imitrex with a note indicating that the sales representative gave Dr. Roos invitation to attend a talk given by Judy Lane as well as Dr. Lane's curriculum vitae, "since I know he has migs himself and Lane would cover questions on kids in her talk."

424. GSK sales representatives lavished special attention on Dr. Brian Grabert, a pediatric neurologist from Colorado Springs, Colorado. Dr. Grabert is a GSK 'thought leader,' routinely detailed on Imitrex for pediatric migraine and Lamictal for bipolar disorder in children.

425. GSK documents reveal that on October 17, 2000, GSK sales representative Betty Hosler detailed Dr. Grabert on the use of Imitrex in children, an off-label use, and "showed him a chart from Clin Ther, said he has some kids that may benefit..." They also discussed "the upcoming ped. talk," in which the "thought leader" would discuss various treatments with other physicians.

426. On December 8, 2000, Hosler followed up with Dr. Grabert bringing him a Christmas wreath and discussing how well his talk with other Colorado pediatricians went; the GSK contact report note indicating: "he said he though it went well told him I appreciated him doing the program because physicians are treating their ped. pts. For [*sic*] migraine using triptans [Imitrex is a "triptan"]; he agreed...."

427. Four days later, Dr. Hosler again visited Grabert, thanked him for his presentation at "the roundtable" and "gave check." On September 13, 2001, a GSK sales representative bought Grabert's office lunch (consisting of 'blimpies') and discussing the use of Imitrex for pediatric migraines. "He agreed he would use more with better technique, nasal is much better than mlts [melts]. Use more 50s and 10ss and has the pts split them to get 25 mg for kids...."

428. On May 8, 2002, GSK sales representative Ron Crews detailed Dr. Grabert on Imitrex and Lamictal and discussed with Grabert the use of Imitrex melts for pediatric migraine.

429. As part of the overall off-label pediatric campaign, GSK had a special marketing niche for Amerge - targeting pediatrics of elementary school age school.

430. Amerge is longer acting than Imitrex and has superior side effect profile, particularly in children. GSK positioned Amerge as the most convenient choice for this age group because a single dose could last throughout the entire school day. GSK also provided sales reps with off-label Faxbacks overtly titled, "Use of Amerge Tablets in Children." *7AC 0000379* and "Use of Imitrex Injection, Tablets, or Nasal Spray In Children." *7AC 0000383-392.*

431. GSK's marketing of Imitrex to pediatrics is particularly outrageous because, as known to GSK, the serious and even life threatening cardiac side effects of the drug are known to be more prevalent in younger patients. As discussed in the pediatric use section of the Imitrex label, Imitrex clinical trials involving pediatrics aged 12 to 17 showed that:

> adverse events observed in these clinical trials were similar to those reported in clinical trials of adults. The frequency of all adverse events in these patients appeared to be dose- and age-dependant, with younger patients reporting events more commonly than older adolescents. Postmarketing experience includes a limited number of reports that describe pediatric patients who have experienced adverse events, some clinically serious, after use of subcutaneous [Imitrex] and/or oral [Imitrex]. These reports include events similar in nature to those reported rarely in adults. A myocardial infarct has been reported in a 14 year old male following the use of oral [Imitrex]; clinical signs occurred within 1 day of drug administration. Since clinical data to determine the frequency of serious adverse events in pediatric patients who might receive injectable, oral, or intranasal [Imitrex] are not presently available, the use of [Imitrex] in patients aged younger than 18 years in not recommended.

432. GSK did attempt to obtain FDA approval of Imitrex Nasal Spray for adolescents. GSK submitted a supplemental NDA to the FDA for that use on February 29, 2000. After four

years and multiple follow up submissions, the FDA deemed the Imitrex SNDA "Not Approvable" on May 24, 2004, concluding:

> the efficacy of Imitrex Nasal Spray has not been demonstrated in adolescents. The adverse event experience essentially mirrored that in the adult data (including rare nasal mucosal changes). Serious but rare events (labeled in adults) have been reported ion adolescents in the post-marketing setting (stroke, myocardial infarction, death in overdose, confusion, gastrointestinal bleeding, and visual loss).

433. Despite the FDA's findings, the unfavorable clinical studies, significant post-marketing adverse event experience, and the FDA-mandated warnings on the drug's label, GSK trained its sales reps to promote Imitrex off-label for pediatrics.

434. Even after the FDA's not approvable decision, internal GSK documents dated April 2005 reveal that GSK knew the drug failed to meet FDA standards for use in pediatrics and presented risks to the pediatric population. *7AC 0000393-0000406.*

C. Use of Peer-to-Peer Marketing to Promote Imitrex and Amerge Off-Label

435. Similar to its off-label marketing of its other prescription products, GSK sought out and compensated physicians it considered ‘thought leaders’ or ‘key opinion leaders’ who were high decile prescribers and likely to influence other health care providers in the community.

436. Arthur C. Roberts, M.D., a psychiatrist from Colorado Springs, Colorado, was paid by GSK to serve on GSK’s “Special Issues Migraine Board,” which met in Las Vegas, Nevada on December 15, 2000, was compensated for speaking about Amerge and Imitrex, and wined and dined at GSK promotions, such as the one that was put together at a local Colorado Springs restaurant on October 4, 2001.

437. Dr. Roberts was encouraged by GSK’s marketing department employees to run his own ‘trials’ concerning the efficacy of Amerge in the treatment of menstrual migraine.

Specifically Relator Greg Thorpe, along with GSK sales representatives Betty Hosler and Joan Schindler concentrated on turning Dr. Roberts into a local headache "thought leader," treating him to dinners and lunches as well as compensating him to lecture on the treatment of migraines. Through his speeches and membership on the "Special Issues Migraine Board" Dr. Roberts influenced other physicians to prescribe Imitrex and Amerge both for indicated and non-indicated uses.

438. GSK also sponsored national speaker programs to promote Imitrex and Amerge. GSK paid nurse practitioner Anna-Lisa Vockell to speak on the use of Imitrex and Amerge for pediatric migraine before the National Primary Care Nurse Symposium at the Keystone Resort in Keystone, Colorado.

439. In addition to recruiting physicians to be local thought leaders, GSK also induced physicians willing to speak in broad terms about the use of Imitrex and Amerge, including the off-label uses of these medications, to become national thought leaders and to help their own practices by sponsoring speaking engagements.

440. Dr. Roger Cady, founder of the "Headache Care Center" in Springfield, Missouri and "Primary Care Network" was another family practice physician who GSK essentially made an overnight "expert" in the headache field with the company's substantial financial help. Cady used his Headache Care Center and his Primary Care Network as his principal means to promote Imitrex and Amerge off-label with the financial backing of GSK. Notably, Primary care Network purports to be a not-for-profit ACCME accredited organization dedicated to providing certified continuing medical education to primary care health clinicians. Since its establishment in 1997, Primary Care Network's philosophy and vision have been to provide primary care healthcare providers, through quality CME, tools they can use to better the health and wellness

of their patients. In reality, Primary Care Network was a sham through which CME events were held to promote Imitrex and Amerge off-label with substantial funding from GSK.

441. GSK's sponsorship of Dr. Cady's CME venture, his lectures, studies and publications, including speeches to GSK's sales representatives at numerous national launch meetings, helped Dr. Cady build his headache specialty practice while Dr. Cady, in exchange, promoted Amerge and Imitrex.

442. Dr. Cady spoke to national groups about off label uses of Imitrex including prophylaxis in menstrual migraine, and use of Imitrex and Amerge for migraine in children. GSK underwrote studies by Dr. Cady including "clinical trials" for off label uses of Imitrex and comparative trials against other drugs in the class. GSK sponsored preceptorships for Dr. Cady and his assistants, and even compensated him to serve on advisory boards.

443. Dr. Cady also co-wrote articles that could be reviewed for CME credit, such as "Migraine Headaches, Part 3, Hormonal Factors." *7AC 0000407-0000410.* This was the third of a three part series of articles on migraine headaches published in July 2003. *Id.* The stated goal of this CME article was "to discuss the work up and treatment of patients with menstrual migraine and migraine during pregnancy." *Id.*

444. Dr. Cady in turn has helped GSK promote Imitrex for off label uses by developing his theory that "sinus headaches" in most cases are really migraines, and that such headaches would respond well to Imitrex. Dr. Cady has made a small fortune as a direct result of GSK's sponsorship. Similar to GSK's support of Dr. Paul Wender, GSK purchased numerous copies of one of Dr. Cady's books for its sales representatives to give to physicians being detailed for Imitrex.

445. GSK also provided significant remuneration to Dr. Robert Kaniecki of Pittsburgh, Pennsylvania, who was probably GSK's most sought after speaker for Imitrex and Amerge. As a neurologist and the director of the Headache Center at the University of Pittsburgh since 2000, and having previously headed up the "Allegheny General Headache Center," Dr. Kaniecki has touted the use of Imitrex - especially the nasal spray form - for its efficacy in the off label use of pediatric migraine.

446. Dr. Kaniecki was the main speaker in at least three of GSK's national launch meetings. GSK has sponsored speaking engagements for Dr. Kaniecki throughout the country: by way of example, GSK flew Dr. Kaniecki to Colorado Springs from Pittsburgh on April 16, 2002 to speak to pediatricians and some family practice doctors on Imitrex and Amerge, including local pediatric neurologist and thought leader Brian Grabert. Internal contact reports such one dated April 4, 2002 indicate that GSK's sales representatives were busy recruiting pediatricians to attend the meeting - the April 4th report indicates that Colorado Springs pediatrician Richard J. Kouri was given "invite to kiniki [sic] pumped it up."

447. Dr. Seymour Diamond and Dr. Merle Diamond, of the Diamond Headache Clinic in Chicago, Illinois, were also national speakers for GSK on the subject of Imitrex and were highly compensated: Seymour Diamond was 'honored' in February of 2003 by GSK for his lifetime contributions to Migraine research. When either of the Diamond doctors were unavailable, Relator Thorpe and other GSK sales representatives utilized Frederick Freitag, D.O. of the Diamond Headache clinic.

448. Moreover, Dr. Merle Diamond was one of the keynote speakers during the December 2000 TSR Training in Las Vegas, referenced above and the slides for which are

attached hereto. His lecture covered Early Intervention and the Use of Imitrex to Treat the Spectrum of Migraine Headache.

D. GSK Targeted Physicians Who Treat Beneficiaries of Government-Funded Healthcare Programs

449. GSK's sales representatives were provided with statistical data relating to specific prescribing physicians and their level of Medicaid prescriptions of specific GSK drugs. These reports also included the number of GSK "details" - visits paid upon the doctor by a GSK sales representative within the reporting period. Significantly, the data GSK reported to its sales representatives often included physicians with specialty areas that could only lead to Medicaid's paying for "off-label" uses.

450. For example, the Imitrex Medicaid Target list (*7AC 0000411-0000412*) and distributed to GSK's sales representatives in the southern Colorado region, contains Medicaid-funded prescription data for the top 50 Medicaid prescribers in that territory. Among the high volume Medicaid prescribers listed who specialize in the treatment of children include pediatric neurologists Brian Grabert and Robin Morgan and pediatrician Richard Kouri. *Id.* The Imitrex tablet Medicaid Market Share for these accounts were 85.3%, 100% and 44% respectively. *Id.* The percentage market share equates the percentage of all triptan and other migraine drugs prescribed by the physician. All of the scripts written by these physicians are off-label because they were written to children, and GSK's aggressive targeting of these physicians caused the submission of these false claims.

451. Moreover, Relators Hamrick and Thorpe witnessed the fact that high decile Medicaid writers would receive greater compensation from sales representatives in the form of free dinners, sporting and entertainment events.

452. Accordingly, GSK's Exploit the Medicaid Bolus campaign was successful and as a result of its off-label Amerge and Imitrex marketing campaigns, caused the submission of false claims to Medicaid and other government programs.

IX. GSK'S OFF-LABEL MARKETING OF LAMICTAL

453. In December 1994, Lamictal (active ingredient *lamotrigine*) was FDA approved for use as adjunctive therapy in adults with partial seizures, and as adjunctive therapy in the generalized seizures of Lennox-Gastaut syndrome in adults and pediatric patients ages two and older.

454. However, despite the narrow indications for which it was approved, GSK heavily marketed Lamictal for the treatment of bipolar disorders both before and during the period it was pending a supplemental new drug application for treatment of bipolar I disorder, which was finally granted by the FDA on June 20, 2003.

A. Off-Label Promotion to Bipolar Patients

455. GSK's aggressive marketing of Lamictal prior to its approval for use in the treatment of bipolar I disorder proved extremely lucrative. Lamictal grew by 33% in the year 2000 (with total U.S. sales of $210 million) and continued to grow in the following years. In a press announcement for year 2003 GSK boasted that Lamictal was approaching "blockbuster status" with sales that grew by 31% to approximately $1 billion.

456. Curiously, there is no data that would support a commensurate rise in partial seizures in adults or Lennox-Gastaut Syndrome, the only approved indications for Lamictal prior to June of 2003.

457. Ultimately, the aggressive and illegal pre-approval marketing served the dual purpose of reaping significant gains prior to approval for treatment of bipolar I disorder as well

as assuring GSK of a nationwide network of health care providers ready to prescribe the drug for bipolar disorders the minute it received FDA approval.

458. Over the course of nearly ten years of off-label marketing of Lamictal, billions of dollars in sales were generated prior to the 2003 indication for bipolar I, as alleged *infra*.

459. Accordingly, GSK, in promoting Lamictal by willfully misrepresenting the FDA approved uses, engaged in egregious and knowing off-label marketing.

1. Off Label Promotion for all Bipolar Disorders

460. Despite the fact that Lamictal was only FDA approved for treatment of partial onset seizures in 1994, since its launch, sales representatives were trained to promote the drug as an effective treatment for all bipolar disorders.

461. Although there are several types of bi-polar disorders, as alleged *infra*, bipolar I is the most severe and the most rare. Notably, the drug was never approved by the FDA for bipolar II disorder or any of the four (4) other variations on bipolar disorder listed below.

- **Bipolar I disorder** involves episodes of severe mood swings, from mania to depression.
- **Bipolar II disorder** is a milder form, involving milder episodes of hypomania that alternate with depression. Bipolar II is a more broadly defined mental illness and encompasses more patients.
- **Cyclothymic disorder** describes even milder mood changes.
- With **mixed bipolar disorder**, there is both mania and depression at the same time, resulting in a person having feelings of grandiosity and racing thoughts, often resulting in an irritable, angry and moody feeling.
- **Rapid-cycling bipolar disorder** is characterized by four or more mood episodes that occur within a 12-month period. Some people experience multiple episodes within a single week, or even within a single day. Rapid cycling tends to develop later in the course of illness. Women are more likely than men to have rapid cycling. A rapid-cycling pattern increases risk for severe depression and suicide attempts.

462. Despite the lack of any bipolar related indication until 2003, sales representatives were provided with materials designed to promote the drug for global bipolar disorders. Even after it received approval for bipolar I disorder in 2003, sales representatives were trained not to call attention to the distinctions among the various types of bipolar disorder unless a physician inquired.

463. As evidence of the pre-indication marketing and training, one need look no further than the 2001 GSK Selling Resource Guide for Lamictal. The Resource Guide provides scripts for sales reps to address requests for information on Lamictal and bipolar depression suggesting that there were numerous inquiries into this usage. *7AC 0000413-0000430.*

464. In furtherance of their bipolar marketing efforts, GSK engaged in an aggressive campaign aimed at pushing sales representatives to use the FaxBack program discussed in the Resource Guide as a marketing tool.

465. Specifically, in the aforementioned 2001 Resource Guide, sales representatives were instructed to direct the physicians to "Faxback Number 5" for information regarding the use of Lamictal and bipolar disorder. This faxback incorporated the findings of Dr. Joseph R. Calabrese, and others, which positively detailed the use of Lamictal in patients suffering from bipolar I and II, mania, unipolar depression, and as a monotherapy. *7AC 0000419*

466. Most troublesome is the fact that GSK was aware of its illegal strategic use of the FaxBack program, yet made a conscious and deliberate effort to cover up its actions.

467. For example, at a management training program in July 2002, Relator Hamrick was instructed by a manager-in-training that, with respect to the detailing of Lamictal for bipolar to psychiatrists, the record of every contact report should <u>automatically</u> include the phrase "Dr.

inquired about bipolar disorder" thereby effectively circumventing the requirements of the FDCA with regards to disseminating literature concerning non-approved uses.

468. In addition to the FaxBacks, GSK frequently distributed "Lit Alerts" to its sales force allegedly for the purpose of educating the drug reps. The Alerts, essentially a cliff-note version of a drug specific study, were routinely carried by sales representatives to aid in answering any questions posed by physicians. The fact that the Lit Alerts were, by their very nature, off label marketing tools, makes their distribution by GSK even more egregious.

469. Specifically, in August 2002, a Lit Alert was distributed to Lamictal sales representatives discussing the use of Lamotrigine as an augmentation agent in treatment resistant depression ("TRD"), a use for which it has never received approval. *7AC 0000431-0000433.*

470. Subsequent to the TRD Lit Alert, in April 2003 GSK distributed another study titled "Lamictal as Maintenance Treatment in Recently Manic or Hypomanic Bipolar I Patients." This Lit Alert served only to fan the flames of an already rampant bipolar campaign and was referenced widely in sales calls. *7AC 0000434-0000438.*

471. Just as troublesome as the Lit Alerts and Faxbacks, were the numerous studies by Calabrese, distributed by GSK, which suggest the efficacy and use of Lamictal in patients with bipolar II.

472. Although Lamictal never received an indication for bipolar II disorder, GSK maintained its effective off label campaign and continued to forge strong relationships with its prescribing physicians ultimately pushing the boundaries by suggesting Lamictal's effectiveness as a treatment option for bipolar II disorder.

473. In fact, since the dosage of Lamictal must be increased slowly from a sub-therapeutic level to a therapeutic level, acute mania and Bipolar II never received an indication.

2. GSK's Improper Use of National Thought Leaders to Promote the Off-Label Marketing of Lamictal

474. GSK's extremely aggressive off-label campaign for Lamictal included spending large sums of money in the form of unrestricted grants, membership on advisory boards and speaker's fees on physicians and researchers who served as "national thought leaders." As with campaigns for other drugs, the campaign for the use of the drug Lamictal in the treatment of bipolar disorders began with the widespread promotion of "disease awareness."

475. Key figures in GSK's national promotion of Lamictal for treatment of bipolar disorders prior to its indication were Dr. Joseph R. Calabrese of Cleveland, Ohio and Dr. Charles L. Bowden of San Antonio, Texas.

476. As previously discussed, Dr. Calabrese, in particular, was GSK's greatest proponent for the use of Lamictal in the treatment of bipolar disorders and published articles advocating the use of Lamictal in bipolar disorder as early as 1998. Dr. Calabrese has widely published his opinion that there is need for a greater awareness of the prevalence of bipolar disorders in the United States, stating that the disease impacts as many as 4% of the total population (11,000,000 people) yet is "largely undiagnosed."

477. In his promotion of the use of Lamictal for bipolar disorder, Dr. Calabrese wrote about a new nomenclature ("above the line/below the line") advocating that Lamictal was clearly superior to other commonly prescribed medications such as Lithium. Dr. Calabrese also defended the drug from the accusation that the risk of serious side-effects, such as Stevens-Johnson Syndrome[4], outweighed the benefits of prescribing the medication.

[4] Stevens-Johnson syndrome is a rare, serious disorder in which the skin and mucous membranes react severely to a medication, in this case, Lamictal, or infection. Often, Stevens-Johnson syndrome begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters, eventually causing the top layer of your skin to die and shed.

478. In addition to journal articles, in 2002 Dr. Calabrese even published a greatly abbreviated, highly commercialized version, of his 1998 study (being careful to identify Lamotrigine by its GSK product title Lamictal) in an internet bulletin called "Fast Breaking Comments." In this interview, Dr. Calabrese blatantly publicizes his determination that "lamotrigine (Lamictal) is effective in the treatment of patients with rapid cycling bipolar II disorder." *7AC 0000439-0000441*.

479. To date, Lamictal has not received an indication for rapid cycling bipolar II disorder. However, GSK placed great emphasis on this study and sales representatives were expected to read and be familiar with Dr. Calabrese's theories and statistics for use in off label marketing.

480. Dr. Bowden began publishing his opinions concerning the efficacy of Lamictal in the treatment of bipolar disorder as early as 1998. Dr. Bowden became a widely sought after speaker for GSK, and GSK sales representatives nationwide were encouraged to try to persuade Dr. Bowden to make presentations on his findings in their geographical area.

3. GSK's Off-Label Marketing to Psychiatrists

481. Seizure disorders – the only approved indication for Lamictal during the 1998 through 2003 period – were treated by neurologists, not psychiatrists. Notwithstanding that fact, GSK began requiring its sales representatives to detail Lamictal with psychiatrists and family practitioners many years before the approval for bipolar I disorder.

482. It is clear that these 'details,' which were prevalent throughout the nation during this period, were directed at persuading physicians to prescribe Lamictal off-label for the treatment of bipolar disorder and through the use of free samples, 'thought leader' lunches, dinners and CME's, and distribution of studies favorable to GSK, particularly the Calabrese

studies, GSK was extremely successful in persuading physicians to begin prescribing the drug off-label.

483. As confirmation of the detailing of psychiatrists, a quick review of the contact sheets written up by the sales representatives shortly after the physician visits confirm the fact that the purpose of these visits was solely to market Lamictal for the treatment of bipolar disorders. The following is representative of the quantity of the off label physician visits by sales representatives including Ron Crews, Joan Schindler and Betty Hosler[5].

- 9/13/00 Dr. Douglas Gregory (psychiatrist) “Had long discussion about Lamictal, is afraid of rash....Rash is severe side effect which has caused death in several patients....“Stevens Johnson Syndrome”....Gave him Calabrese article and encouraged him to talk to Marciniak [local GKS “thought leader”;

- 10/18/00 Dr. McClure [Dr. Scott H. McClure, psychiatrist] Is getting more comf w/ lamic, thought it [conference put on by GSK]was informative More comfortable with Lamictal for bi-polar;

- 10/26/00 Dr. Crandall (psychiatrist) "[D]iscussed Bowdens' lecture, she is afraid of the rash;

- 10/30/00 Dr. Gamblin (psychiatrist) "very pos. about lam. (Lamictal) has over 50 patients on it”..."Trained with Bowden sorry he missed it " (referring to lecture in Colorado Springs that GSK arranged with Dr. Bowden as the speakers);

- 10/30/00 Dr. McClure [Dr. Scott H. McClure, psychiatrist] "Said he is more comf. with Lamictal as monotherapy [in the treatment of bipolar disorder] after hearing Bowden likes the bottles of 25 only, not the kits (Lamictal) samples”;

- 1/8/01 Dr. Harazin [Dr. Jeffrey Harazin, psychiatrist] "Lamictal is on it's way";

- 03/21/01 Dr. Marciniak [psychiatrist] detailed by GSK District Manager for Lamictal in bipolar;

- 05/23/01 Dr. Gregory [psychiatrist] attended noon lecture at Pikes Peak Mental Health with Dr. Paul Wender speaking, detailed on Lamictal;

[5] These notes have been reproduced exactly as they were written in the contact reports by the individual sales representatives and entered into the Passport system following each sales call.

- 06/12/01 Dr. Gamblin [psychiatrist] again detailed on Lamictal;
- 06/19/01 Dr. Richard Marciniak [psychiatrist] detailed on Lamictal and offered a free fly fishing trip;
- 06/21/01 Dr. Richard Marciniak again detailed on Lamictal and offered speaker/dinner engagement at local restaurant (Warehouse);
- 07/05/01 Dr. Gamblin again detailed for Lamictal;
- 07/19/01 Dr. Richard Marciniak again detailed on Lamictal and stated it is his choice for treatment of bipolar, as well as discussing dosage amounts and titration;
- 07/30/01 Dr. Fred Michel detailed on the use of Lamictal for the treatment of children ("Uses very little Lamictal in kids but would like to use it more.");
- 03/14/02 Dr. Julie Sanford [psychiatrist] detailed for using Lamictal in the treatment of bipolar;
- 03/15/02 Dr. Gamblin had not yet seen the Calabrese study but did not want to drive to Denver for CME's;
- 03/15/02 Dr. James Spadoni [psychiatrist] detailed for the use of Lamictal in bipolar;
- 03/19/02 Dr. Marciniak agreed to be paid by GSK to speak about Lamictal for bipolar as well as Wellbutrin at a lunch for local physicians in Colorado Springs;
- 03/19/02 Dr. Stephen Mueller [psychiatrist] confirmed attendance at the bipolar/Lamictal physician's meeting in Colorado Springs, Colorado;
- 03/20/02 Dr. Gamblin again detailed for prescribing Lamictal for bipolar disorder;
- 04/03/02 Dr. Marciniak detailed for Lamictal and confirmed that he would accept paid assignment to do GSK's CME program on June 7, 2002;
- 04/03/02 Dr. Spadoni [psychiatrist] detailed for use of Lamictal in bipolar disorder;
- 04/10/02 Dr. Gamblin detailed for use of Lamictal in bipolar disorder with reference to the Calabreze study;
- 04/24/02 Dr. David Caster [psychiatrist] detailed for Lamictal in bipolar disorder;

- 04/25/02 Dr. Rosalyn Kneppel [psychiatrist] detailed for Lamictal in bipolar disorder;

- 04/29/02 Dr. Nancy Sharpe, a Colorado Springs psychiatrist, was detailed for Lamictal in bipolar disorder; this doctor, who has a large Medicaid practice, asked the GSK sales representative about proper dosage amounts;

- 05/01/02 Dr. Brian Grabert, a pediatric neurologist, was invited to be on GSK's advisory board for an upcoming San Diego, California conference;

- 05/06/02 Dr. Gamblin detailed once again for Lamictal and now said he feels quite comfortable using it;

- 05/08/02 Dr. Rosalyn Kneppel [psychiatrist] again detailed for Lamictal in bipolar disorder;

- 05/08/02 Dr. Jeffrey Harazin again detailed for Lamictal in bipolar and now said he uses it 'first line' for bipolar disorder;

- 05/13/02 Dr. Stephen Mueller, psychiatrist, again detailed for Lamictal in bipolar and requested pricing information;

- 05/17/02 Dr. Marciniak agreed to do a talk and stated that he is using Lamictal more for bipolar now that he has more samples;

- 05/20/02 Dr. Elliott Cohen, psychiatrist, detailed for Lamictal and he requested more samples;

- 05/20/02 Dr. Rosalyn Kneppel [psychiatrist] again detailed for Lamictal in bipolar disorder and said she is using half the dosage [recommended for seizures] because of concerns about the rash;

- 05/20/02 Dr. James Polo detailed for use of Lamictal in bipolar disorder in adolescents;

- 05/22/02 Dr. Ralph Everett, child psychiatrist detailed for Lamictal in bipolar and after having stated he did not like it, was given a comparison to Zoloft by the GSK rep;

- 05/22/02 Dr. Scott McClure, psychiatrist, again detailed for Lamictal in bipolar and Dr. McClure asked the GSK rep. how to dose if a patient was already on Depakote for bipolar and was given 'the Calabrese study' by the rep;

- 05/23/02 Psychiatrists Dr. Anne League, Dr. James Spadoni and Dr. Julie Sanford were treated to lunch at a local Colorado Springs restaurant by the GSK sales

representative and given American Psychiatric Association guidelines relating to Lamictal;

- 05/23/02 Psychiatrist Pamela A. Brickers of Colorado Springs, CO was detailed by a GSK representative and was given a copy of "the calabrfese [*sic*] study";
- 05/29/02 Dr. Julie Sanford was detailed on Lamictal for bipolar and the GSK rep went over a study/comparison with Zoloft that was favorable to GSK's product;
- 05/29/02 Dr. James Spadoni and Dr. Richard Marciniak detailed for Lamictal;
- 05/30/02 Dr. Brian Grabert detailed for Lamictal for his pediatric patients;
- 06/05/02 Dr. Brian Grabert again detailed for Lamictal and discussed the rash;
- 06/17/02 Dr. Honie Crandell again detailed for Lamictal in the treatment of bipolar disorder and confirms that it is her drug of choice for this disorder.

484. In addition to targeting psychiatrists for detailing, prior to the FDA approved indication for bipolar I, GSK sales representatives were instructed to devote virtually all of their free sampling activities to psychiatrists, rather than neurologists. A routine practice that was documented in the contact reports of physician details as well as the first-hand experience of Relator Thorpe.

B. GSK'S Off-Label Promotion of Lamictal Resulted in Patient Harm

485. Although the FDA issued recommended dosing for Lamictal for its seizure indications, there were no such dosing guidelines for use in patients suffering from any form of bipolar disorder prior to the FDA approval in 2003. As such, there existed an acute risk of overdosing and resulting complications.

486. Since the FDA did not establish a recommended dosage for Lamictal for use off label, and because the potential side effects were so severe if not dosed correctly, once the sales representatives had successfully gotten a physician to inquire about its use for bipolar, they were instructed to use the phrase "start low and go slow."

487. On information and belief, this "catchphrase" came directly from the GSK marketing department and was used by sales representatives throughout the country as a way to remind physicians to start with a small dose and raise the dosage very slowly in the treatment of bipolar I disorder in children and adolescents especially.

488. Given the lack of dosing information, coupled with the intense campaign for use as a treatment for bipolar disorders, the contact reports referenced in the preceding paragraphs evidence physicians routinely inquiring about dosage and titration from the sales representatives themselves.

489. On information and belief, as a direct and proximate result of the lack of proper dosing of Lamictal when used off-label, patients suffered both reported and unreported severe side effects including death.

490. The Federal Drug and Cosmetic Act ("FDCA") and its regulations require that adverse events due to prescription medications be promptly reported. However, ample evidence exists of widespread under-reporting of adverse drug reactions, even when drugs are being prescribed for their approved uses. (Mintzes, B., Bassett, K., Wright J.M.. Drug Safety without Borders: Concerns about Bupropion. *Can. Med. Assoc. J.*, 2002;167(5); Moride Y, Haramburu F, Requejo AA, Begaud B. Under-reporting of Adverse Drug Reactions in General Practice. *Br J Clin Pharmacol* 1997;43(2):177-81; Bates DW. Drugs and Adverse Drug Reactions. How Worried Should We Be? *JAMA* 1998;279(15):1216-7; Okie, S., Safety in Numbers - Monitoring Risk in Approved Drugs, *N.E.J.M.*, 352:1173-1176, March 2005.)

491. On February 14, 2003, Relator Hamrick became aware of an incident involving the dangers of off-label prescription particularly when combined with the widespread laxity in adverse event reporting when he called on Dr. J. Vitanza, an allergist.

492. Mr. Hamrick was informed that one of Dr. Vitanza's patients had been prescribed Lamictal for bipolar I disorder (prior to its approval by the FDA) and noted in the patient's chart an incidence of rash. Assuming that the patient's psychiatrist would report the rash incident, Dr. Vitanza failed to report the occurrence to the FDA. After observing that the physician was not going to file an adverse event report, Mr. Hamrick filed his own, based upon his second-hand knowledge of the incident. *7AC 0000442-0000443.*

493. As a result of the underreporting of rash occurrences, physicians failed to be properly alerted to the potential danger of the rash which had, on a few occurrences, developed into Stevens-Johnson Syndrome.

494. In addition to the unreported incidents of rash, often resulting from off-label prescriptions, at least one death resulted from the use Lamictal for bipolar I disorder.

495. Dr. Julie Sanford, a psychiatrist who was consistently detailed by GSK sales representatives to prescribe Lamictal for bipolar disorders, prescribed the drug for a patient that subsequently died. Since Dr. Sanford was not a neurologist likely to be treating a patient for a seizure disorder, it should have been apparent to GSK officials receiving a copy of her adverse event report that the drug was, in all likelihood, prescribed for a non-indicated use.

496. Nevertheless, in a May 22, 2001 letter to Dr. Sanford from GKS's "Global Clinical Safety and Pharmacovigilance" division, there is a reiteration of adverse event reporting: the patient, who had been given Lamictal experienced headache and died, and other patients of whom she was aware also experienced rashes subsequent to receiving therapy with Lamictal. *7AC 0000444***.**

497. Significantly, the "Global Clinical Safety and Pharmacovigilance" division, while allegedly interested "in obtaining as much information as possible concerning reports of

suspected adverse reactions for the purpose of continuing to monitor and evaluate drug safety" made no inquiry into the issue of the purpose of the supposed therapy.

498. Of even more concern, in a conversation with Relator Thorpe, Dr. Sanford, a psychiatrist married to key opinion leader Dr. Marciniak, revealed that the patient who died was in fact being treated for bipolar I disorder.

499. Clearly, when combined with the lack of recommended dosage, the off-label use of Lamictal made for a recklessly dangerous combination for patients resulting in severe rashes, including Stevens Johnson Syndrome, and even death.

C. GSK Targeted Federal Health Care Programs for Off-Label Use

500. GSK's off-label marketing tactics also helped put their products on Tricare/Champus formularies for uses not approved by the FDA.

501. For example, GSK focused on psychiatrist Dr. James Polo because of his position at Evans Army Hospital, Fort Carson, Colorado. As a result of the persistence of GSK, Lamictal was actually placed on formulary for treatment of bipolar disorders prior to receiving such an indication.

502. GSK began seriously attempting to influence Dr. Polo in the late 1990's by making arrangements for and paying for all of the food and liquor at the annual Colorado Spring Psychiatric Association Christmas party at Dr. Polo's home, with 60-70 physicians in attendance.

503. A simple review of just a few GSK contact reports in 2001 and 2002 clearly indicates that GSK sales representatives "detailed" Dr. Polo to enlist his aid in placing Lamictal on the Tricare/Champus formulary at Fort Carson for use in the treatment of bipolar disorders:

- 4/23/02 Dr. James Polo detailed on Lamictal and Wellbutrin, invited to GSK speakers program, "he saw the green journal and asked if on lamictal on formulary, he said yes but for neurology only; he will champion it for p.t."

- 5/20/02 Dr. James Polo detailed on Lamictal with note "he was not attending the Tricare meeting this week, wsr for pts. w depression and concentration difficulties, lamictal is now a favorite of his and uses it in adol with bi-polar."

- 7/15/02 Dr. James Polo detailed on Lamictal and reported that "Lamictal is no longer restricted to neurology" meaning it was now available on the Tricare formulary.

- 07/24/02 Dr. James Polo detailed on Wellbutrin and Lamictal and reported "Lamictal free for all psyches.'

504. As evidence of the success of the GSK engineered approval of Lamictal for use as a psychiatric treatment on the Fort Carson Tricare formulary, Dr. Kenneth Gamblin, a high volume Medicaid psychiatrist was told, (according to the July 17, 2002 GSK contact report) about availability of Lamictal on the Tricare formulary. Subsequently, according to the aforementioned contact report, he "...has started several new pts."

505. Upon information and belief, GSK targeted other high volume federal healthcare providers for off-label use of Lamictal and by the second quarter of 2007, Lamictal held a 14.1% share of the Medicaid market.

X. GSK'S OFF-LABEL MARKETING OF LOTRONEX

506. On February 9, 2000, the FDA granted a narrow indication for Lotronex for the treatment of Irritable Bowl Syndrome ("IBS") in adult women whose predominate bowl symptom is diarrhea.

507. Following the FDA's determination that Lotronex posed a serious and significant public health concern, the drug was pulled from the market.

508. Two years later, in June 2002, Lotronex was reintroduced with availability and use restricted, making it the first drug ever returned to the U.S. market after withdrawal for safety concerns.

509. Disturbingly, the very narrow approval for Lotronex had a negligible impact on their marketing efforts. In fact, 6 to 9 months prior to its approval, GSK had already begun a systematic indoctrination of its sales force with the message that Lotronex had blockbuster potential and, as such, they should commence marketing to physicians without waiting for FDA approval of the then pending NDA.

510. As such, when, at the end of 1999, GSK (then Glaxo Wellcome) failed to meet the double digit sales growth it had predicted for that year, the company realized the necessity of attempting to get whatever new products it had into the stream of commerce.

511. Consequently, GSK inundated its sales force with messaging for Lotronex prior to any approvals, and despite the potentially lethal side effects. As a result of the pre-indication push however, GSK managed to post $30 million in sales in a mere 90 days.

512. On June 30, 1999, when GSK publically announced the submission of its New Drug Application ("NDA") for Lotronex, it concomitantly noted to its shareholders, and the rest of the general public, that IBS was one of the most commonly diagnosed disorders and that, as a result, "IBS sufferers may be falling through the cracks of the healthcare system".

513. An integral part of the Lotronex marketing effort involved teaching the sales representatives how prevalent but under-recognized IBS is. As part of the "educational process", reps were provided with Faxbacks and other promotional materials which attempted to broaden the indications for the, as of then, unapproved drug. Such materials included articles supporting the use of Lotronex for the treatment of IBS *in men*—a group for whom approval was never received.

514. In fact, as part of the public announcement regarding the NDA, the company even promoted the fact that a "large trial" involving men was about to commence. Notably, the results of that "trial" were never released or used in marketing.

515. In addition to the Faxbacks, GSK distributed a detailed list of "signs" and "symptoms" of IBS to its sales representatives for use in detailing physicians, ostensibly hoping to develop what it had categorized the "under-recognized patient."

A. GSK Compensated Physicians to Lecture Off-Label on Lotronex

516. As with the marketing of its other prescription medications, GSK relied heavily upon financial incentives and paid physician speakers for the promotion of Lotronex and for the purpose of inducing fellow physicians to prescribe for both on and off-label uses.

517. Namely, in their effort to bolster the pre-approval sales of Lotronex, GSK employed Dr. Lin Chang of UCLA as a consultant and speaker on Lotronex and IBS in women.

518. Dr. Chang's engagement with GSK was not limited to speaking engagements, in fact she conducted studies promoting the efficacy of Lotronex which were distributed for use by the sales force, and remained a GSK consultant even after Lotronex was withdrawn from the market due to the occurrence of serious life-threatening side effects.

519. Similarly, GSK provided financial incentives including paid preceptorships, compensation for speaking tours, and free entertainment including lavish dinners, fishing trips etc. to physicians including Dr. Gerard Guillory of Lake Charles, Louisiana, Dr. Abbass Shafii of Colorado Springs, CO, and Dr. Ronald Fass of Tucson, Arizona.

520. The excesses to which GSK went were exemplified by Dr. Guillory. Although his practice is in Aurora, Colorado, the doctor was flown by GSK to his hometown of Lake

Charles for a ‘speaking engagement’ with another physician and some GSK sales representatives. This trip included complementary travel, dinners and fishing.

521. As further evidence of the kickback strategy employed by GSK to promote Lotronex, one need look no further than the aptly named "Lotronex Launch" meeting in Las Vegas, Nevada in March of 2000.

522. About two weeks prior to the launch meeting, and in the presence of Relator Hamrick, District Sales Manager Pat Keith promised Dr. Ian Levenson that if he became a leading prescriber of Lotronex, GSK would provide him with a free round of golf at either the Canyons TPC, or Royal Links, both exclusive country clubs in Las Vegas. Additionally, while Dr. Levenson attended the Lotronex Launch, GSK catered a full dinner for his family at his personal residence.

B. Marketing of Lotronex Off-Label to Men

523. As part of the Lotronex off-label marketing plan, GSK asked its sales representatives to try to specifically identify male physicians who would themselves admit to suffering from IBS symptoms.

524. Both Relators Thorpe and Hamrick were in fact instructed to tell the targeted physicians that since a majority of IBS patients were female, studies were ongoing in males and had not yet been completed.

525. GSK continued to push Lotronex for men despite the fact that studies on the drug never demonstrated its effectiveness in that population.

526. Despite the overwhelming evidence against effectiveness in men, male physicians with IBS were encouraged to “try it on themselves to see if it works…it could not hurt and might

help…" Ultimately, the scheme behind this marketing ploy was that if a physician happened to respond to Lotronex, he would be much more likely to prescribe it for his male patients.

527. After receiving instructions to market toward adult men, Relator Thorpe asked at least three male physicians in Colorado Springs, Colorado to try Lotronex and, ultimately, one of these physicians felt that it worked well enough on himself that he began prescribing it to his male patients.

XI. GSK'S OFF-LABEL MARKETING OF PAXIL

528. Beginning in at least 1994 and continuing through 2004, GSK and its wholly owned subsidiary SmithKlineBeecham ("SKB"), promoted Paxil off-label for a multitude of uses for children, adults and pregnant women.

529. In some instances, such as certain anxiety disorders detailed herein, Paxil received FDA approval but the marketing of the drug far predated the FDA approval. In other instances, such as promotion for children and pregnant women, the drug was never FDA approved. In fact, GSK marketed Paxil for these uses despite its knowledge that the drug was dangerous when used in the manner in which GSK was promoting it.

1. Paxil's Approval History

530. Paxil was first approved by the FDA on December 29, 1992 for the treatment of MDD in adults. Thereafter, Paxil received additional approvals for the following uses for adults only:

- May 7, 1996 - Obsessive Compulsive Disorder ("OCD");
- May 7, 1996 - Panic Disorder;
- May 11, 1999 - Social Anxiety Disorder ("SAD");
- April 13, 2001 - Generalized Anxiety Disorder ("GAD")

- December 14, 2001 - Post Traumatic Stress Disorder ("PTSD")-
- October 2, 2002 - longer term use for GAD

531. The FDA initially approved the extended release formulation of Paxil, called Paxil CR, on February 16, 1999, for the treatment of MDD. Thereafter, Paxil CR received approval for Panic Disorder, Social Anxiety Disorder, and Premenstrual Dysphoric Disorder.

532. The FDA has not approved either Paxil or Paxil CR for any use in pediatrics because every study conducted to date on pediatric Paxil use has concluded that the drug is not effective. Moreover, those studies conclude there are serious risks when used in the pediatric population, in particular an increased risk of suicide.

533. In 2002, at or near the peak of the off-label campaign, Paxil was the leading antidepressant on the market, generating billions of dollars in sales annually.

2. GSK's Seamless Continuation of SKB's Off-Label Paxil and Paxil CR Promotion Post Merger

534. Relator Thorpe first became aware of the unlawful Paxil off-label marketing scheme as early as 1994, because Paxil was a top competitor of GSK's antidepressant, Wellbutrin, which Relator Thorpe promoted.

535. As a result of this head-to-head competition between Paxil and Wellbutrin, GSK reps and Paxil reps typically detailed the same physicians. As a result, Relator Thorpe would sometimes be present in a physician's office at the same time as a Paxil rep. Therefore, he witnessed the SKB sales rep's detailing tactics and off-label marketing of Paxil, as well as the sampling of Paxil off-label, particularly to pediatricians.

536. In 2000, GSK acquired SKB and SKB merged into GSK. After the merger, GSK reorganized the sales force to accommodate the addition of a second antidepressant, Paxil, to its portfolio.

537. GSK made its 'Therapeutic Area Specialists,' a specialty sales force one tier above GSK sales representatives, responsible for detailing Paxil and Wellbutrin to physician specialists, including psychiatrists and physicians specializing in pediatric care. In Colorado, the Therapeutic Area Specialists included Betty Hosler, Joan Schindler and Ron Crews, among others.

538. Since the GSK representatives selling Wellbutrin did not get any bonus for Paxil and vice versa, sales representatives targeted the drugs for different disease states. For example, Paxil would be targeted for depression, anxiety and social phobia issues in children and in adults, and Wellbutrin SR would be sold for ADHD, depression and bipolar disorder.

539. GSK sales representatives also marketed Paxil for co-morbid disease states. A child with depression and symptoms of anxiety might be a good candidate for Paxil, whereas a child with depression who needed an 'energy boost' would be a good candidate for Wellbutrin, since Wellbutrin was believed to impact Norepinephrine and Dopamine.

540. GSK marketed both Paxil and Wellbutrin for bipolar disorder and ADHD, however Wellbutrin was perceived to be the leader in off-label use for ADHD.

541. GSK management was well aware that off-label promotion of Paxil remained rampant post merger. For example, Relator Greg Thorpe's District Manager, Pat Keith, had direct knowledge of the unlawful marketing, because he discussed the issue with Relator Thorpe and other GSK sales representatives.

542. GSK allowed the promotion to continue post merger however because the company reaped huge financial benefits there from. By 2003, Paxil sales had soared and it became the biggest seller worldwide, posting impressive sales of $2.7 billion in the U.S. alone.

3. Off-Label Promotion of Paxil and Paxil CR to Children

543. A primary component of the off-label marketing campaign for Paxil, both before and after the GSK-SKB merger, was marketing the drug for a litany of uses in pediatric patients, including depression, anxiety and ADHD. To effectuate this scheme, Paxil sales reps aggressively targeted and sampled Paxil to pediatricians and pediatric specialists as well as other physicians who treat children.

544. Relator Thorpe was an eyewitness to this unlawful and dangerous marketing of Paxil to children from approximately 1994 through 2002.

545. Before the merger, Relator Thorpe witnessed Paxil sales reps detailing Paxil off-label to pediatricians. Most notably, this occurred in the offices of Dr. Fred Michel, who was one of the largest volume prescribers of psychiatric medications to pediatric patients in the Colorado Springs area. Moreover, all of the pediatric psychiatrists in Colorado Springs, as well as physicians who treated large numbers of children, including Ralph Everett M.D., Scott McClure M.D., Jeffrey Rinsky M.D., Elliott Cohen M.D., Anne League M.D., and David Elwonger M.D., were "targeted" physicians by GSK marketing. GSK management was aware, and in fact endorsed, these off-label Paxil marketing efforts.

546. Relators Thorpe and Hamrick also observed that space in the sample closets of physicians who treated children for psychiatric disorders was shared between Wellbutrin SR and Paxil.

547. Contact reports from the GSK database, accessed by Relator Thorpe during his employment, corroborate that GSK continued to actively market Paxil to pediatricians following the merger.

548. By way of example, contact reports reveal that on May 19, 2003 and again on August 20, 2003, Dr. Jordan R. Kline, a Denver area pediatrician, was detailed by a GSK sales representative for the use of Paxil in adolescents with depression. On September 19, 2002, pediatrician Nathaniel J. Moore, MD of Greenwood Village, Colorado was detailed by a GSK sales representative on the use of Paxil for kids.

549. Greg Thorpe, based upon his experience derived from marketing Wellbutrin, believes that sales reps selling Paxil nationwide were likewise armed with journal articles similar to the Wellbutrin Faxbacks that were delivered or sent to physicians by GSK sales representatives, containing small "studies" of limited significance or anecdotal information suggesting that Paxil was useful for non-indicated treatments such as pediatric depression as well as off-label adult use as alleged herein.

550. GSK continued marketing of Paxil for pediatric use, despite its knowledge of the significant suicide danger and serious adverse event potential that the drug posed when prescribed for children, adolescents and adults, which was evidenced when an unbiased account of GSK’s 329 study finally came to light.

551. Indeed, GSK's subsidiary SKB, conducted at least 3 focused studies on pediatric use of Paxil for depression: Study 329, Study 377 and Study 701. Studies 329 and 377 were completed in November 1998. Study 701 was completed in July 2001.

552. All three of these studies proved that: 1) Paxil was no more effective than placebo for pediatrics (in fact in Study 701, placebo outperformed Paxil) and 2) Paxil users experienced up to a three fold increase in the risk of self-harming behavior, including suicide.

553. In response, GSK buried the results of Studies 377 and 701. GSK allowed Study 329 to be published Journal of the American Academy of Child and Adolescent Psychiatry, the

study authors massaged the data. They dramatically downplayed the negative findings and exaggerated the scant "positive" findings to contrive support for their paradoxical conclusion that "Paroxetine is generally well-tolerated and effective for major depression in adolescents."

554. Upon information and belief, the falsified results of Study 329 were used by sales reps to promote Paxil off-label for use in children.

555. It was not until June 19, 2003 that the truth about Paxil came to light. Still, GSK successfully stifled Studies 377 and 701 until they were finally published in 2006. On or about that date, the FDA warned that patients under the age of 18 should not take Paxil because of the heightened risk of suicide.

556. On or about September 14, 2004, the FDA voted to extend that warning to all antidepressants, mandating that all manufacturers of antidepressants to add a black box warning to their product labeling disclosing this increased risk of suicide in pediatrics. Paxil's label now reads:

Suicidality and Antidepressant Drugs

> Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of PAXIL or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. PAXIL is not approved for use in pediatric patients. (See WARNINGS: Clinical Worsening and Suicide Risk, PRECAUTIONS: Information for Patients, and PRECAUTIONS: Pediatric Use.)

4. Marketing of Paxil and Paxil CR Off-Label to Adults

557. GSK and SKB promoted Paxil for the following off-label use: premature ejaculation and general social phobias, anxiety, ADHD, shyness, bipolar disorder and bipolar depression.

558. Further, as stated above, Paxil was initially approved in 1992 for the treatment of major depressive disorder and years later received supplemental approvals for OCD, panic disorder, SAD, GAD and PTSD. However, Relator Thorpe witnessed GSK/SKB market Paxil for each of these uses beginning in 1994, which is years before the FDA approved Paxil for these uses. As with SKB's promotion for other off-label uses detailed herein, Relator Thorpe witnessed this off-label promotion while on sales calls for GSK, while attending SKB symposiums, and he discussed SKB's off-label promotional tactics with Paxil sales reps.

559. In addition, during and after the SKB/GSK merger, at national conferences attended by Relator Thorpe, it was suggested that Wellbutrin and Paxil could complement each other if sold together, because Wellbutrin in smaller doses could be used to counteract the sexual side effects known to occur with SSRIs such as Paxil. However, Paxil is not approved as an adjunctive antidepressant therapy.

560. GSK developed national physician speakers for both Paxil and Wellbutrin to promote the off-label adjunctive use of Paxil.

561. GSK also promoted Paxil as a non-addicting SSRI, despite the company's inside knowledge garnered through adverse event reports that showed significant instances of patient withdrawal. These reports noted severe withdrawal reactions, including the heightened risk of suicide, dizziness and vertigo, nausea, vomiting, aggression, irritability, memory and concentration difficulties.

562. One way the drug was promoted in this manner was by comparing the drug's safety profile to another anti-depressant manufactured by GSK, Wellbutrin, when the company knew that Wellbutrin could be stopped immediately, but that Paxil could not. GSK concealed its knowledge of Paxil's serious side effects to prevent harm to drug sales; however, the adverse events eventually became so significant that the FDA required GSK to change the drug's label to identify the serious withdraw symptoms associated with the drug. Not only did GSK detail heavily off label during this time frame, but messages were sent from the marketing department to "**downplay**" the side effects of drugs, not inform the physician for the patients' safety and well-being. This "marketing strategy" was used with all products in this complaint, according to Relators. Side effects and potential serious problems with GSK products were to be "downplayed", and as recently shown with Paxil studies including study 329, actually hidden from the physician.

563. Relators have personal knowledge that this materially false and misleading claim that the drug was non-addictive was made from at least 1998/1999 and continued up to the time Relator Thorpe was terminated from GSK.

564. GSK also promoted Paxil as safe for use during pregnancy, when the company knew or recklessly disregarded that the drug significantly increased the risk of birth defects, in particular, congenital abnormalities.

565. As part of this scheme, GSK routinely provided Paxil samples to Obstetricians with the intent for women to commence Paxil therapy, a fact that was witnessed by Relator Thorpe during sales calls to Obstetricians and observations of such physicians' sample closets. Relator Hamrick also witnessed a wealth of Paxil samples in pediatricians sample closets during sales calls.

566. In fact, marketing to obstetricians was encouraged by GSK as evidenced by the Spring 2004 "Compass" newsletter. *7AC 0000445-0000450.* Published by GSK on a monthly basis, The Compass provides information concerning brand strategy, customer targeting and information about plans of action. Also included in this newsletter are "Target Types" designed to "help you determine the basic focus of your message to the customer". Notably, for Paxil CR, reps are supposed to target "High PMDD[6] Potential" which is explained as "customers who are either OBGYNs or heavy writers on women's health. They have been prescribing Paxil and have a high potential of using Paxil CR for PMDD."

567. As previously discussed, Paxil has never received any indication for PMDD and is, as explained *infra*, a high risk pregnancy drug.

568. Additional evidence of GSK's internal push to off-label OBGYN marketing can be seen in the "Sales Planning & Performance" document from November 2003 which specifies OBGYNs as a specialty for the "Anti-Depressant (Paxil) Market".

569. Initially, Paxil was classified as a Category C pregnancy drug, meaning the drug has no known link to increased birth defects. It was not until September 2005 that GSK began to come clean in a Dear Doctor letter disclosing the increased risk of congenital birth defects in pregnancy women taking Paxil.

570. The September 2005 Dear Doctor letter was prompted by a GSK-funded study commenced in 2003. The study was a retroactive analysis of pregnant women, dating back to 1995, who had taken antidepressants in the first trimester of pregnancy and given birth to infants with major congenital malformations. The study concluded that Paxil users experienced a two-fold increase in birth defects as compared to women taking other antidepressants.

[6] PMDD is an acronym for Premenstrual Dysphoric Disorder

571. GSK's Dear Doctor letter was insufficient to warn of the serious risks Paxil posed to unborn children. In December 2005, the FDA strengthened the warning and ultimately reclassified the drug to a Category D, which is reserved for drugs with positive evidence of fetal risk. Notably, Paxil is the only SSRI of that class of drug classified as a Category D drug.

5. GSK's Off-Label Promotion of Paxil and Paxil CR Caused Substantial Improper Medicaid Expenditures

572. The total amount of Medicaid Sales for Paxil from 1997 through 2004 amounted to $2,718,004,000.00.

573. Relator Thorpe believes that approximately 20%-30% of Paxil's Medicaid sales have been for off-label use based upon his personal observations. When combined with other government-funded healthcare programs including Medicare Part D, CHAMPUS, and CHAPVA, among others, the total amount of off label Paxil sales approach or exceed $1 billion dollars.

XII. GSK'S OFF-LABEL MARKETING OF VALTREX

574. In 1995, Valtrex (valacyclovir hydrochloride) received its first two narrow indications. The first indication was received on June 24, 1995 for the treatment of herpes zoster (shingles) in adults, and the second in December 1995 for the treatment of acute attacks of recurrent herpes simplex (genital herpes).

575. Ultimately, Valtrex received the following additional indications:

- October 9, 1996: For 10 day treatment of first episode genital herpes
- September 26, 1997: For use in the suppression of recurrent episodes of genital herpes in immunocompetent adults for up to six months.
- September 9, 2002: Treatment of herpes labialis (cold sores) in adults and adolescents ages 12 and older.

- April 1, 2003: For use in the suppression of recurrent genital herpes in HIV infected adults.

- August 9, 2003: For use in combination with safe sex to reduce risk of transmission of genital herpes during suppressive therapy of the source partner in a heterosexual couple.

- September 2, 2008: For the treatment of chickenpox in children ages 2-18 years of age.

576. As soon as it received a single FDA indication, and without regard to the limitations of that indication, GSK immediately began an ambitious program marketing Valtrex for additional off-label uses.

577. As with its other off-label marketing projects, the Valtrex "brand strategy" paid off handsomely and sales grew from 199 million pounds (approximately $383 million) to 242 million pounds (approximately $465 million) from 1999 to 2000.

578. In fact, the off-label "brand strategy" worked so well, that by the end of 2003, GSK's sales of Valtrex approached $1 billion, prompting the company to state that the drug was reaching "blockbuster status".

579. By the second quarter of 2007, not only had Valtrex proven a successful brand for GSK, it also boasted a 61.8% Medicaid market share indicating a successful and widespread campaign to Medicaid prescribing practitioners.

580. Beginning in 2000, GSK launched a massive educational campaign for its sales representatives to familiarize them with the various off-label uses of Valtrex that were being pushed as a part of the marketing program. For many of these off-label uses, GSK never intended to submit supplemental new drug applications. To date, these off-label uses have not been approved, including the use of Valtrex in the treatment of Bell's Palsy, and multiple sclerosis, as

well as for prophylactic use in the 2nd and 3rd trimesters of pregnancy to prevent transmission to the fetus.

1. GSK Violated The Anti-Kickback Statute Through Its Systematic Compensation of Physician Speakers For Off-Label Programs On Valtrex

581. GSK utilized its Regional Medical Scientists, paid physician speakers, lavish speaker training programs, sponsorship of entertainment and sporting events and frequent detailing of physicians by GSK's sales representatives for off-label uses of Valtrex in order to accomplish its ambitious goal of widespread prescription of this drug.

582. GSK sales representatives who had first line responsibilities for detailing Valtrex frequently treated doctors to sporting events. For example, on April 2, 2002, Dr. Kurt Lesh, a family practitioner was visited by GSK sales rep Jim Butler who stated in his contact report that he invited Dr. Lesh to a Colorado Avalanche hockey game and, although he had to decline because of another appointment, Butler reported that he "told him to write more Valtrex because he owes me; he agreed...." Similar contact reports abound – by way of example, Dr. David Roos of Aurora, Colorado detailed for Valtrex for cold sores on October 21, 2002.

583. Taking a page from its proverbial "playbook" when it initiated marketing efforts for Valtrex, GSK began by emphasizing herpes as an under-recognized disease state. This initial categorization paved the way for a nationwide campaign highlighting a multitude of additional off-label uses for the drug.

584. As part of the launch for their nationwide campaign, in November 2000, GSK distributed a taped presentation to its sales force to educate them on off-label uses of Valtrex and to encourage them to begin detailing physicians for these uses. *7AC 0000451-0000464.*

585. The lecture/presentation featured a GSK paid physician ‘expert' who begins by emphasizing that although there are at least 45 million Americans with herpes, the true figures could reach 1 in 4 Americans if it weren’t for the fact that the disease is under-recognized by health care practitioners. *7AC 0000451*.

586. During the course of this taped presentation, the lecturers, Dr. Peter Leone from the University of North Carolina, Dr. Bob Deiter, and Terry Warren, a nurse practitioner from Portland, Oregon discussed various off-label subjects, including once daily therapy for cold sores, over six months use for suppressive therapy, and use for prophylaxis, none of which were approved at that time.

587. Notwithstanding an initial disclaimer about not utilizing the information on the tape to detail physicians, the tape was a pep talk for the GSK sales representatives to support what the GSK presenter called GSK's "brand strategy" for Valtrex and included statements such as:

- "We have a medical information department that will focus on supporting the ‘brand strategy' for Valtrex..."
- "You will also see medical information get a lot involved in sales training...."
- "How can the sales force hammer home their message with clinicians? ... I would certainly stress that suppression is underused- no reason why people should not do long term suppression more than 6 months...."
- Notwithstanding pro forma disclosures about not utilizing the information for detailing physicians, the tape ended with the following from the GSK presenter: "Dr. Leone, Dr. Deiter, and Nurse Practitioner Warren sure hit the

nail on the head. It sounds like a blueprint for success. What about you? Ready to build better sales?"

588. On July 24, 2000, another memorandum issued to GSK's Cerenex, CNS (central nervous system) and TS (therapy specialists) sales forces nationwide from the Valtrex marketing department, detailed a study from the Centers for Disease Control that implied the importance of Valtrex as suppressive and prophylactic therapy. *7AC 0000465.*

587. The clear intent in disseminating such a study was to supplement GSK's off-label marketing efforts by supplying its sales force with material which it could use to help bolster sales.

588. Key national thought leaders including Dr. Judith Reynolds and Dr. Robert Weber of Colorado, a noted Colorado Springs infectious disease specialist, were paid significant remuneration to spread the word on Valtrex for off-label uses through lectures to other physicians.

589. In addition to being handsomely paid for speaking to other physicians, Dr. Weber was treated to expensive meals and sports events as part of GSK's drive to promote Valtrex, with his physician speaker engagements carefully arranged and overseen by former GSK sales representative Kris Joyce.

590. Another notable and extravagant expenditure on lavish entertainment to entice physicians to prescribe Valtrex was the Billy Joel/Elton John concert at the Pepsi Center in Denver on April 9, 2001.

591. This event, promoted by District Sales Manager Pat Keith, engaged Ken Lichtenstein, M.D., to enjoy the spectacular concert in the comfort of a luxury box while discussing the many uses of Valtrex with the other invited physicians. Part of the presentation

included a PowerPoint designed by Dr. Ken Greenberg, one of Dr. Lichtenstein's partners at the time, a presentation that was ultimately used by numerous GSK compensated speakers including Dr. Ben Young.

592. On information and belief, Dr. Young also continues to enjoy compensation from GSK as a result of his speaking engagements and, as recently as the second quarter of 2009 earned an impressive $33,500 in speaker fees.

593. Not only did GSK utilize their high profile physician speakers to hawk Valtrex for unapproved uses, the company also encouraged sales representatives to make abundant use of "Faxback" materials and to rely on off-label studies by GSK's Regional Medical Scientists. Notably, these Regional Medical Scientists were oftentimes paid GSK employees with either a doctorate of pharmacy or an M.D.

2. GSK Promoted Valtrex Off-Label for Lifetime Suppression

593. Both before and after receiving the indication in September 1997 for use as a suppressive therapy for recurrent genital herpes, GSK latched on to the "suppression" message in a clear effort to make Valtrex a "lifetime" drug for patients who suffer from genital herpes.

594. This "lifetime" marketing strategy is exemplified in a Marketing Update PowerPoint presentation from 2000. The presentation itself focuses entirely on "How to Sell Suppression" and includes messaging on brand strategy which should be to "Encourage physicians, PA's, & NP's to offer ALL appropriate pts [sic] the option of *Suppressive Therapy*." *7AC 0000466-0000472; 7AC 0000475-0000490.*

595. Although Valtrex received an indication for suppression in 1997, it was not approved for lifetime use, and in fact the package insert even contains a statement that "The

safety and efficacy of [suppressive] therapy with VALTREX beyond 1 year have not been established."

596. Despite the fact that the PI clearly indicates the lack of approvals or efficacy studies beyond 1 year, the aforementioned audio tape presentation by Dr. Deiter, et al., and the Marketing Update presentation repeatedly emphasized a lifetime suppression application for Valtrex, a use that clearly extended far beyond the FDA's approved indications.

XIII. GSK'S OFF-LABEL MARKETING OF WELLBUTRIN IR, WELLBUTRIN SR AND WELLBUTRIN XL

597. GSK manufactures and markets 3 formulations of Wellbutrin: Wellbutrin IR, Wellbutrin SR and Wellbutrin XL.

598. The FDA approved Wellbutrin IR (immediate release) on December 30, 1985 for the treatment of Major Depressive Disorder ("MDD").

599. On October 4, 1996, the FDA approved Wellbutrin SR (sustained release) tablets for the treatment of MDD in adults.

600. Subsequently, in 2003, the FDA approved the use of Wellbutrin XL (extended release) for the treatment of MDD in adults.

601. Wellbutrin, Wellbutrin SR and Wellbutrin XL have never received FDA approval for pediatric use.

602. The off-label sales and marketing of Wellbutrin alleged in this complaint primarily relate to Wellbutrin SR and Wellbutrin XL. Indeed, as the patent expiration for Wellbutrin SR neared, GSK aggressively promoted physicians to switch from Wellbutrin SR to Wellbutrin XL for both on and off-label use. Sales reps promoted these switches under the guise that Wellbutrin XL, a once daily pill, was a more convenient choice. However, GSK's true

purpose was to preserve precious Wellbutrin market share jeopardized by competition from generic forms of Wellbutrin SR.

603. When used in this complaint, the term Wellbutrin shall refer to all of the drug's formulations collectively.

604. Wellbutrin SR was a big-seller for GSK, surpassing the billion dollar sales benchmark in 2001. The sales success of Wellbutrin, Wellbutrin SR and Wellbutrin XL can be attributed in large part to GSK's off-label marketing campaign.

605. Wellbutrin's mechanism of action is unique from the other top selling antidepressants on the market. The most prescribed antidepressants are selective serotonin reuptake inhibitors, otherwise known as SSRIs. Examples of SSRIs include Zoloft, Prozac, Lexapro, Paxil, and Celexa. Wellbutrin, however, is not believed to affect serotonin levels in the brain and instead is believed to affect norepinephrine and dopamine levels.

606. As a result, GSK faced resistance from doctors to using Wellbutrin as a front line antidepressant. To overcome this resistance and generate additional sales, GSK marketed the drug for off-label use as detailed herein. In particular, GSK sought to create the misperception that Wellbutrin was superior to SSRIs, by promoting the drug off-label as having positive effect on sexual functioning. GSK chose this strategy because weight gain and sexual dysfunction are the "Achilles heels" of SSRIs.

607. By means of payments to physicians through grants, preceptorships, membership on therapeutic specialty boards, as well as attempts to curry favor with physicians through gifts of free tickets to professional sports events and other premier entertainment events, GSK was extremely successful from 1997 throughout the time alleged in this complaint, in causing Medicaid, Tricare/CHAMPUS and the other government-funded health care plans to pay vast

sums of money for Wellbutrin prescribed to beneficiaries of those publicly-funded healthcare programs for off-label use, including pediatric psychological disorders, pain (GSK had a Faxback devoted to the use of Wellbutrin for the treatment of pain), anxiety, adult weight loss, Attention Deficit Hyperactivity Disorder (ADHD) in adults and children, co-administration with SSRIs, sexual dysfunction, treatment of depression in pregnant women, bipolar disorder and sundry addictive disorders, including smoking cessation.

608. Wellbutrin has also been successfully pushed by GSK sales representatives for 'co-morbid' disorders, such as depression *and* lack of sexual desire, depression *and* addiction to tobacco products, or depression *and* weight gain, violating FDA regulations governing approved indications.

1. Off-Label Promotion of Wellbutrin as the "Happy, Horny, Skinny Drug"

609. From the time of the drug's launch, GSK unlawfully promoted Wellbutrin for weight loss and improved sexual functioning. GSK also marketed Wellbutrin as a superior first line antidepressant to SSRIs because of its purported ability to cause these positive side effects. Alternatively, GSK promoted the drug off-label as an adjunctive therapy to an SSRI, to "cure" the sexual dysfunction and weight gain side effects frequently associated with SSRI use.

610. By 2001, GSK made weight and sexual functioning the focus of the core sales message for Wellbutrin. *7AC 0000492.*

611. On December 4, 2000, at a regional meeting of GSK sales representatives in Las Vegas, Nevada, former Regional Vice President of sales Roger Hawley coined the Wellbutrin catchphrase ultimately adopted nationwide to promote the drug in this manner. During the meeting, RVP Hawley told the sales representatives that there were "five reasons to get a commitment from a physician to prescribe Wellbutrin SR: 1. feel better, 2. lose weight, 3. stop

smoking, 4. get more energy and 5. enjoy an increased libido....We need to let physicians know that Wellbutrin SR is the 'Happy, Horny, Skinny drug....'"

612. Sales reps nationwide incorporated the "happy, horny, skinny drug" marketing slogan into their sales repertoire as a means to promote Wellbutrin SR off label, but in a catchy, "humorous," attention-grabbing manner. It was a great success. The slogan was easy to recall and physicians repeated the phrase among themselves or back to representatives.

613. In a manner parallel to its off-label marketing scheme for Advair and Lamictal, GSK trained its sales representatives how to promote off-label uses of Wellbutrin. To confirm the success of this training, GSK required its representatives to pass tests on the off-label uses or face termination.

614. For example, a document entitled "Lit Alert: Impact of Bupropion SR on Weight Loss in Nondepressed Obese Patients" was distributed to GSK sales representatives on August 14, 2002. *7AC 0000509-0000511.* The Lit Alert summarized the results of the GSK-funded study, which identified a dose-related weight loss concomitant with Wellbutrin SR use. *Id.*

615. Although GSK included its usual "disclaimer" that the material was not to be taken to physician's offices for detailing, it tested its sales representatives on this information and required at least an 85% correct score on the thirty-five question test in order to maintain employment. *Id.*

616. Significantly, the study which was the subject of this Lit Alert, which sales reps used to promote Wellbutrin SR for weight loss, would not have been of the quality that could cause the FDA to approve such an indication.

617. In using the Lit Alert during sales calls, Wellbutrin sales representatives were instructed not to call attention to the "negative" aspects of the study, specifically, that evidence of

weight loss ceased after 48 weeks, that the subjects were already in a program that included exercise and dietary supplements, or that GSK underwrote this study.

618. The slide show presented by Dr. Ken Fujioka during the GSK National Meeting held in San Diego, California from July 15-17, 2001 titled "Effects of Bupropion on Body Weight" is yet another example of GSK's thorough training of sales representatives on Wellbutrin's effectiveness for weight loss. *7AC 0000741-0000752*.

619. Dr. Fujioka's specialty is weight loss, not depression, as he was the Director of Weight Loss and Metabolic Research at the Scripps Clinic. *7AC 0000741*.

620. Relator Thorpe was present Dr. Fujioka's presentation of the slides. All sales representatives in attendance received a paper copy of the presentation, which GSK - not Fujioka - authored.

621. As the title indicates, the slideshow showcased Wellbutrin study data establishing the drug's effectiveness for weight loss. *Id.* Indeed, it even featured the results of Wellbutrin "Obesity Trials," despite the fact that these clinical trials did not include even a single depressed patient in the study group. *7AC 0000745*. Not surprisingly, these studies concluded *inter alia* that "Bupropion is more effective than placebo in achieving weight loss in non-depressed obese patients." *7AC 0000748.*

622. This presentation also features the results of the 2001 Gadde study, discussed *infra*, which subsequently formed the basis for the Gadde Reprints, which in turn became a key off-label promotional tool used by sales reps to promote Wellbutrin for weight loss during sales calls.

623. GSK's purpose in hiring a specialist in the weight loss field to present Wellbutrin weight loss data to sales reps at a National Meeting is patently clear - use this data promote Wellbutrin off-label for weight loss.

624. In addition to Lit Alerts described *supra*, GSK also provided sales representatives with multiple Faxbacks discussing off-label studies to provide "scientific" support for the promotion of Wellbutrin for weight loss, and lack of sexual side effects. The following are two examples of GSK off-label Faxbacks used for this unlawful purpose:

- *FaxBack #20* - "Effects of Wellbutrin SR on Body Weight," which discusses Wellbutrin's positive effect on weight when used for depression, smoking cessation and obesity. *7AC 0000512-0000518.*
- *Faxback # 21* - "Transfer from an Other Antidepressants to Wellbutrin SR," which discusses in principal part switches from SSRIs to resolve sexual dysfunction side effects, to increase sexual desire and to improve orgasm functioning. *7AC 0000526-0000532.*
- "Use of Wellbutrin SR in Combination with Selective Serotonin Reuptake Inhibitors," which purports to corroborate that "the combination of bupropion with sertraline [Zoloft], fluoxetine [Paxil] or paroxetine may be effective in patients refactory to these drugs alone and that the addition of bupropion to ongoing therapy with an SSRI may be effective in reversing SSRI-induce sexual dysfunction." *7AC 0000533-0000538.*

625. Off-label detailing by GSK sales reps, including the tactics of using such off-label Faxbacks, was effective for GSK and translated into off-label prescriptions. For example, according to the contact report of GSK sales rep Anne Cutter dated September 12, 2000, she called upon Colorado Springs psychiatrist Dr. Richard Marcinak exclusively on Wellbutrin.

According to the notes, "did lunch with office went over off-label use with wbsr and how I can sell it to primaries he has not had many formulary issues with it."

626. Peer-to-Peer marketing was also a central component of GSK's off-label Wellbutrin campaign, including heavy reliance upon GSK "national thought leaders." "National thought leaders" are a higher order of speaker and therefore GSK paid them at a markedly higher rate for their services. In many instances, these speakers did not become "national thought leaders" until after GSK financed their speaking engagements and studies through grants, preceptorships, and other forms of remuneration.

627. Examples of this practice abound, but one "national thought leader," Brendon Montano, began as a family practice physician. After paid participation in GSK's Wellbutrin promotion programs, he eventually became well-known as a speaker in the area of depression and weight loss, depression and loss of sexual desire and depression generally.

628. In addition to significant remuneration in the form of speaker engagements for promoting Wellbutrin for weight loss and sexual dysfunction, usually at $2,000 to $2,500 a shot, GSK kept Dr. Montano incentivized with other gifts, such as an all-expense paid ski trip to Colorado on January 19, 2002, to accompany a group of other physicians on a ski trip to Breckenridge, Colorado, including free meals, lift tickets and lodging.

629. Dr. Montano once boasted to Relator Thorpe that he could fly free of charge anywhere he desired because of the abundance of airline miles he accumulated on GSK's national speaking tours.

630. Another prominent physician highly compensated by GSK to speak positively to other physicians about the increased libido effect of Wellbutrin SR was Dr. Harry Croft of San

Antonio, Texas, who was recruited to speak in Colorado by GSK sales representative Betty Hosler.

631. Still other "national thought leaders" got their start in academia, where GSK: financed their research on unapproved indications for GSK's Wellbutrin, helped distribute the information nationwide to physicians, and then paid them to speak nationally to physicians about the results support the studied off-label use.

632. For example, GSK financed studies performed by Dr. Kishore Gadde of Duke University Medical Center on the use of bupropion (Wellbutrin's chemical name), in weight loss. GSK's payments to Dr. Gadde began with a weight loss study in 1999 financed by GSK, with preliminary results announced nationwide by GSK, and followed with articles published in the journal *Obesity Research*, Vol. 10, No. 7 (July, 2002) and Vol. 10, No. 10 (October 2002).

633. GSK converted Gadde's biased research into reprints for sales reps to use to promote Wellbutrin for weight loss during sales calls. Wellbutrin sales representatives were provided the Gadde Report as part of the Wellbutrin Home Study Guide Q4 '01. *7AC 0000539*. As with the aforementioned Lit Alert, sales representatives were required to study and memorize the Gadde Reprint and other materials on weight change, among other material provided in the Home Study Kit, and then to pass a certification exam with a minimum score of 85%. *Id.*

634. In addition to his GSK-funded research, Dr. Gadde was elevated to a member of GSK's national speaker's bureau and served as a consultant to predecessor company Glaxo Wellcome. As of 2003, however, Dr. Gadde fell out of favor as a national speaker.

635. Another physician picked from the university setting and paid large sums to be on GSK's lecture circuit for Wellbutrin was Dr. James Hudziak, a psychiatrist currently at the University of Vermont. Besides funding clinical studies, GSK compensated Dr. Hudziak, who

was on of the most sought after speakers, to speak on the off-label uses of Wellbutrin. Relator Thorpe set up a conference for Dr. Hudziak on September 18, 1999 at the Broadmoor Hotel in Colorado Springs, Colorado.

636. GSK carefully scripted its promotional speaker programs. Among other things, GSK provided all speakers with a Slide Lecture Kit for use in connection with speaking engagements. Included in these Slide Kits were PowerPoint slide shows and speakers were expected to present these slides as packaged. Relator Thorpe is in possession of a copy GSK's Management of Depression Slide Kit which was in circulation during his employment. The GSK slides corroborate that GSK speakers routinely promoted Wellbutrin's positive effect on weight and sexual function. *7AC 0000542-0000647.*

637. GSK also created the program called "P.R.I.D.E." (an acronym for "Peer Review of Intimacy, Depression and Efficacy") in furtherance of its marketing of Wellbutrin for off-label use. *7AC 0000648*. GSK paid substantial speaker fees to national thought leaders such as Dr. Brendan Montano to make presentations on national teleconferences touting the efficacy Wellbutrin for the treatment of sexual dysfunction and depression. Such presentations were thinly veiled commercial messages for the use of bupropion in co-morbid states of depression and sexual dysfunction and depression and cigarette addiction.

638. Each conference consisted of a live 45 minute presentation followed by a 15 minute question and answer session. Conference speakers included Montano and Dr. P. Murali Doraiswamy, a Duke University researcher who co-authored articles such as "Effect of BupropionSR on the Quality of Life of Elderly Depressed Patients with Comorbid Medical Disorders" (1999), and "Mood Disorders and Chronic Obstructive Pulmonary Disease: Current Research and Future Needs" (2002).

639. To support the P.R.I.D.E. program, the entire GSK sales staff received special slide kits like the one attached as *7AC 0000542-0000647* to coordinate with the physician "peer to peer" program and to help present Wellbutrin's effectiveness for off-label uses.

640. GSK frequently utilized visual presentations prepared by Dr. James Pradko to market Wellbutrin off-label. Pradko was a highly compensated nationwide speaker for GSK. GSK paid him at one point over $500,000 a year to promote GSK products off-label. For example, GSK representative Betty Hosler set up a physician-lecture on off-label uses of Wellbutrin by Dr. Pradko in Denver on June 10, 2000. As enticement to attend this off-label presentation, Hosler arranged for complimentary tickets at Cirque du Soleil for all conference participants immediately following the lecture.

2. Off-Label Promotion for ADHD in Children and Adults

641. Psychiatrist Dr. Paul H. Wender, MD, was yet another highly paid national speaker for GSK's off-label promotion of Wellbutrin, however, his focus was the promotion of Wellbutrin for ADHD in Children and Adults. Dr. Wender authored a book titled "ADHD Attention-Deficit Hyperactivity Disorder in Children, Adolescents, and Adults," which explicitly endorsed the off-label use of bupropion for the treatment of ADHD in children and in adults. GSK purchased multiple copies of Dr. Wender's book and distributed these copies to its sales force.

642. GSK's Marketing Development Managers ("MDM") and Regional Medical Scientists ("RMS") worked together to promote the use of Wellbutrin SR for the treatment of ADHD in adults and children. GSK MDMs and RMSs recognized the value Dr. Wender added to that effort. Accordingly, GSK paid Dr. Wender to speak all across the country, including in

Denver, Colorado, Tucson, Arizona, and Phoenix, Arizona, about the benefits of Wellbutrin for the treatment of ADHD.

643. For example, on May 23, 2001, Dr. Wender gave a luncheon speech sponsored by GSK at Pikes Peak Mental Health at which he discussed the efficacy of Wellbutrin in the treatment of children with ADHD. GSK chose this facility because it was known to treat predominantly Medicaid/Tricare beneficiaries.

644. Other key "thought leaders" were paid handsomely by GSK to speak to physicians on off-label use of the drug Wellbutrin on a local level. Dr. Fred Michel, a pediatric psychiatrist, was paid by GSK to speak to physicians in the Colorado Springs area to promote the use of Wellbutrin for the treatment of ADHD in children. Dr. Michel was a high decile prescriber for GSK with a large number of Medicaid and Champus patients in his practice.

645. For example, GSK sponsored a lecture given by Dr. Michel to a nationwide audience of approximately 2000 nurse practitioners as part of the Nurse Practitioners Symposium held on July 3, 2003 in Breckenridge, Colorado. Dr. Michel's lecture, "ADHD across the Lifespan," primarily focused on the treatment of ADHD, with an emphasis on pediatric treatment.

646. In addition to heavy use of speaker programs to promote Wellbutrin for ADHD, sales reps aggressively detailed pediatric specialists to promote this off-label use in children, as GSK contact reports confirm. The following is a summary of some of the instances in which GSK sales representatives detailed pediatric specialists for off-label uses of Wellbutrin's prescription medications for children:

- On October 20, 2000, Dr. Fred Michel, a Colorado Springs psychiatrist was detailed by GSK sales representative Betty Hosler who discussed with him the use of Wellbutrin for children. Dr. Michel told Hosler he used Wellbutrin for children as young as

age five. Dr. Michel quickly became a "thought leader" for GSK. On February 14, 2001, he presented a program on GSK's behalf to Pikes Peak Mental Health advocating the use of Wellbutrin for the treatment of ADHD in children, attended -- according to the contact report -- by 60 doctors and therapists with a note indicating "will see results from this." The program was specifically approved by GSK District Sales Manager Pat Keith and at corporate headquarters by Glaxo Wellcome Speaker Events.

- On July 30, 2001, Dr. Michel was detailed by GSK sales representative Ron Crews for Wellbutrin SR and Lamictal; in the notes Crews indicated that "they are using a lot of wsr in kids but more in adults,...."

- On September 12, 2001, Dr. Charon S. Nelson of Colorado Springs was detailed by GSK sales representative Ron Crews for Wellbutrin SR with a note indicating that a fax back was utilized for prescription of Wellbutrin for "anxiety" and that "she uses a lot of 100 mg to start kids on for ahdh and comorbid depression."

- On September 24, 2001, Dr. Charon S. Nelson of Colorado Springs was again detailed by GSK sales representative Ron Crews and sampled with Imitrex and Wellbutrin SR samples with a note that indicates "asked her to consider wsr when thinking of a ssri. She agreed and took it further and painted several pt pictures. She uses 5-6 mg/kg for kids who have depression and adhd."

- On September 27, 2001, GSK sales representative Ron Crews telephoned Dr. James Polo of Evans Army Hospital in Colorado Springs, Colorado and asked "when we could do a talk with his peers about wsr in kids, looks like nov. at the earliest, wants the slide kit and any medical info. to add."

647. Such marketing tactics were not reserved for pediatric specialists. for example, on September 12, 2000, a GSK sales representative detailed Dr. Julie Sanford of Colorado Springs, CO. According to Ms. Cutter's contact report, "did lunch with office went over many uses of wbsr from add, adhd, addiction, and weight loss. likes the drug had to leave before I had commitment." *7AC 0000649*.

648. GSK also provided its sales force Faxbacks to "substantiate" Wellbutrin as a safe and effective drug for ADHD, just as it did for other off-label uses described above. Faxback # 12, titled "Use of Wellbutrin SR for the Treatment of Attention Deficit Hyperactivity Disorder, summarized "a small number of controlled and uncontrolled" studies concluding that Wellbutrin SR is effective for the treatment of ADHD in children and adults. *7AC 0000650-0000653.*

649. In addition to supplying off-label Faxbacks for ADHD, GSK also provided training to those sales reps about the content of such Faxbacks, including the TSR Representatives Training held on December 5, 2000. *7AC 0000654-0000657.*

3. Off-Label Promotion of Wellbutrin for Depressive Symptoms, Including Anxiety

650. Depression and anxiety disorders are separate and distinct according to the Diagnostic and Statistical Manual of Mental Disorders, otherwise known as the DSM-IV. There are multiple types of depressive disorders, including Major Depressive Disorder, which is the only form of depression Wellbutrin is indicated to treat. Similarly, there are multiple types of anxiety disorders recognized by the DSM-IV, including panic disorder, obsessive-compulsive disorder, post-traumatic stress disorder, generalized anxiety disorder, socialized anxiety disorder and phobias (social phobia, agoraphobia, and specific phobia).

651. Wellbutrin is not indicated to treat any anxiety disorder, nor is it indicated to treat any symptoms of anxiety comorbid to major depressive disorder.

652. As known by GSK, however, people with depression often experience symptoms similar to those of an anxiety disorder, such as nervousness, irritability and problems sleeping and concentrating. Available scientific data indicates that roughly half of depressed patients also suffer from anxiety or symptoms of anxiety.

653. Recognizing a lucrative market opportunity so closely tied to depression, GSK aggressively marketed Wellbutrin off-label for anxiety.

654. GSK provided sales representatives with brand support to further this improper marketing scheme, both in terms of training materials explaining how to market the drug off-label for anxiety symptoms and marketing materials such as Faxbacks for use in promoting co-morbid anxiety during sales calls.

655. For example, the Wellbutrin Semester II – 2001 Selling Resource Training manual makes repeated reference to marketing the drug for anxiety, including suggested scripted features and benefits of the drug to repeat to doctors to obtain their assent to prescribing Wellbutrin for anxiety symptoms. Among the most overt scripted questions includes the following:

- Feature: In comparative studies of WELLBUTRIN SR, an NDRI, and Zoloft, an SSRI, both antidepressants reduced depression-related anxiety symptoms by 50% on the HAM-A over an eight week period, although neither separated from placebo.

- Benefit: This means your depressed patients experiencing anxiety symptoms associated with their depression you can confidently prescribe WELLBUTRIN SR and expect effects in depression associated anxiety comparable to ZOLOFT[7]; and,

- Doctor, how do you choose an antidepressant for the depressed patient who also presents with depression-related anxiety and lethargy symptoms?

7AC 0000495-0000496; 7AC 0000497.

656. These suggested verbatims are particularly significant because GSK did not even bother indicating these off-label solicitations were not for use only response to an unsolicited question.

657. Faxback #15 titled "Wellbutrin SR for the Treatment of Anxiety" is one example of the sales tools available to sales reps during sales calls. *7AC 0000658-0000665.* This Faxback purports to provide scientific evidence that supports the following conclusions. Similarly, the Faxback titled "Efficacy and Safety of Wellbutrin SR Compared to Sertraline [Zoloft]," also touts that "Wellbutrin SR and sertraline were similarly effective in treating depression and accompanying symptoms of anxiety in all three studies." *7AC 0000666-0000676.* The Faxback titled "Efficacy and Safety of Wellbutrin SR Relative to other

[7] Notably, at this tie Zoloft was FDA approved for several anxiety disorders, including PTSD, panic disorder, adult and pediatric OCD and PMDD.

Antidepressants," drew the same conclusion, except in this Faxback, Wellbutrin SR's "significant improvement in symptoms of depression and accompanying anxiety" was compared to that found with Paxil. *7AC 0000677.*

658. According to the GSK's Selling Resource Guide Semester II – 2001 for Wellbutrin, the Croft Reprint, (WEL778), the Coleman Reprint (WEL783) and the Wellbutrin Detail Aid (WEL774), known as the Cars Detail Aid, all also contain support for Wellbutrin's efficacy for use in the treatment of anxiety symptoms with depression. *7AC 0000506*. Indeed, the Selling Resource sets forth a scripted selling scenario on how to effectively market Wellbutrin's effectiveness on anxiety symptoms. *Id.*

659. GSK also used its speaker programs to promote Wellbutrin for off-label use. The Wellbutrin slide kit referenced *supra*, titled Depression Management Slide Kit, also includes an entire section of slides devoted to touting Wellbutrin's effectiveness for anxiety. The slide includes the language, "In severely depressed patients, bupropion was effective in treating depression and accompanying anxiety." See *infra*.

660. Notably, GSK did not mark this slide as for use only in response to unsolicited questions. Instead it appears to be part of the standard PowerPoint presentation.

4. Off-Label Promotion of Wellbutrin for Smoking Cessation

661. GSK also made a concerted effort to promote Wellbutrin for smoking cessation.

662. After physicians treating depressed patients happened to observe that Wellbutrin sometimes made it easier for patients to stop smoking cigarettes, GSK undertook a campaign to market the drug as a cessation took under the commercial name Zyban.

663. Despite the fact that the use of Zyban for smoking cessation was eventually banned in Europe, GSK continued to push its use here, utilizing many of the same physician speakers it used for the promotion of Wellbutrin for weight loss and sexual dysfunction.

664. GSK was complicit in physician use of "Wellbutrin" rather than "Zyban" for smoking cessation, because, although basically the same product, many public and private insurers do not cover drugs prescribed for smoking cessation. For example, the Medicaid statute expressly prohibits payment for smoking cessation and weight loss treatments of any kind, including prescription medications. Accordingly, while a public insurer such as Medicaid would deny coverage for Zyban, because its approved use is smoking cessation, Medicaid would cover Wellbutrin, because the reimbursement claim does not identify the purpose for which the drug was prescribed.

665. GSK also covertly utilized free drug samples in its effort to market Wellbutrin for smoking cessation.

666. Early in 2001, the United Kingdom reported an alarming number (over 5,000) of adverse events and subsequently took Zyban off the market. Nevertheless, that same year GSK distributed to its sales force "Zyban Target Lists for Qtr 1 2001" listing the highest decile Zyban prescribing physicians. Simultaneously, Greg Thorpe and other sales representatives detailing physicians for Wellbutrin received *quadruple* the number of Wellbutrin samples. There is no explanation for this practice other than as a part of GSK's continuing effort to expand its Wellbutrin sales to include treatment for smoking cessation.

5. Off-Label Promotion to Obstetricians

667. GSK also directed its sales representatives to detail Wellbutrin heavily to obstetricians for use in prescribing the drug to pregnant women. As part of this effort, GSK

created physician target lists for Wellbutrin that focused on obstetricians. GSK instructed its sales representatives to assure physicians that Wellbutrin SR was safe for use in pregnant women, despite the fact that it was rated 'Category B' with respect to pregnancy, indicating it had undergone animal studies but there are no studies involving the drug in pregnant women.

6. GSK's Off-Label Marketing Efforts Targeted High Volume Medicaid and Tricare Providers

668. GSK's marketing scheme for Wellbutrin was enormously successful, resulting in a 20% increases from 1999 to 2000, and continued increases through 2003 with total Wellbutrin SR and XL sales again increasing by approximately 20% in 2003. As GSK boasted in its preliminary announcement of year-end results for 2001: "Wellbutrin's sales grew strongly, up 37% to £647 million [1.24 billion dollars] driven by increase physician awareness of the product's outstanding efficacy and favourable side effect profile in non-anxious depressed patients." Largely as a result of the aggressive off-label marketing campaign, GSK did not suffer the long-anticipated decrease in sales due to generic competition until year 2004.

669. Much of this success is attributable to the substantial marketing efforts GSK geared towards "high decile" Medicaid providers. In furtherance of this marketing effort, GSK sales reps were given Medicaid Targeting Data reports. These reports identified the largest volume prescribers of GSK drugs, including Wellbutrin, to Medicaid beneficiaries. This type of targeting was an essential component of GSK's mentality to "Exploit the Bolus" of public payors such as Medicaid and Tricare.

670. For example, attached to the First Amended Complaint as Exhibit 2 is a Wellbutrin SR "Medicaid Targeting Data" spreadsheet distributed to GSK sales representatives on July 20, 2002. *7AC 0000683.* This physician targeting tool identifies by name and zip code the Top 50 Medicaid Prescribers. The report also identifies the number of sales calls and

detailed Medicaid prescription information, including the total dollar value of prescriptions written to Medicaid beneficiaries for both Wellbutrin and Wellbutrin SR.

671. Pediatric specialist Fred Michel is the second highest Medicaid prescriber for Wellbutrin on the July 2002 report. *Id.* This is significant because all the Medicaid expenditures for Wellbutrin prescribed by Dr. Michel were for pediatric patients thereby making them ineligible for reimbursement and accordingly constituting false claims under the false claims acts of the government plaintiffs. Accordingly, GSK's targeted marketing efforts towards Dr. Michel caused the submission of these false, ineligible Wellbutrin reimbursement claims to Medicaid, which Medicaid was improperly induced to pay.

672. Another way GSK sought to gain market share among Medicaid prescribers was through GSK sales practices and particularly frequent detailing, arranging physician ‘peer-to peer' meetings, use of ‘local thought leaders' as well as the use of well-known national speakers and printed materials dealing with off-label, unapproved indications.

673. For example, on April 10, 2002, Dr. Kenneth Gamblin, a Colorado psychiatrist, told a GSK sales representative that was detailing him that "he really enjoyed dinner last night, he thinks Marciniak [local thought leader Dr. Marciniak] is very bright, he needs to use more wsr [Wellbutrin SR]...gave him Calabrese study [for Lamictal in bipolar disorder] and we will go over it next time." This was memorialized in a sales rep contact report. Dr. Gamblin was a prominent "target" for GSK because, as noted in the confidential contact report of May 24, 2002, "he is the highest rxr of anti-depressants" and Gamblin was encouraged to "use Wellbutrin where you use ssris [selective serotonin re-uptake inhibitors] for depression, Lamictal cala [Calabrese] study again]." Dr. Gamblin, as indicated in GSK's target lists, was also one of the region's highest Medicaid prescribers.

XIV. GENERAL VIOLATIONS

A. GSK's Systematic Violation of The Anti-Kickback Statute In Its Marketing Activities

674. As stated earlier, during the period alleged in this Seventh Amended Complaint, GSK paid doctors in cash and in kind with the purpose and intent for those physicians to prescribe GSK drugs.

675. In addition to the P.R.I.D.E. program for promotion of Wellbutrin, GSK instituted an earlier program called "FIRST" (an acronym for "Fast Innovative Relief that is Safe and Tolerable") for the promotion of Imitrex. *7AC 0000684.*

676. For this program, GSK sales representatives recruited physicians without prior speaking experience, had them attend an initial training session, then paid them to speak to other doctors about headache relief, utilizing GSK's slide shows and demonstrative aids.

677. In addition, GSK would pay large sums to doctors in compensation, up to $25,000, for their participation in advisory boards.

678. GSK also utilized somewhat more subtle forms of remuneration including preceptorships, lavish entertainment and sporting events, personal use of free samples of GSK prescription medications and massive lunch programs involving GSK representatives routinely taking entire clinic staffs to lunch.

679. All of the aforementioned forms of remuneration constitute kickbacks. Specifics concerning the kickback schemes for each category of remuneration is described below:

1. National Speakers

680. GSK provided significant compensation to physicians in exchange for their promotion of GSK’s prescription drug products.

681. These national speakers include: Roger Cady, MD, Springfield, MO (speaker for off-label uses of Imitrex); Kathleen Farmer, Psy.D.; Springfield, MO (speaker for off-label uses of Imitrex); Judy Lane, MD, Denver, CO (speaker for off-label uses of Imitrex); Harry Croft, MD, San Antonio, TX (speaker for off label uses of Wellbutrin SR/Lamictal); Anita Clayton, MD, Charlottesville, VA (speakers for off label uses of Wellbutrin SR/ Lamictal); P. Murali Doraiswamy, MD, Durham, NC (speaker for off label uses of Wellbutrin SR/ Lamictal); Robert Golden, MD, Chapel Hill NC (speaker for off label uses of Wellbutrin SR, Lamictal); Michael Thase, MD, Pittsburgh PA (speaker for off label uses of Wellbutrin SR/Lamictal); Jeanne Wolfe, MD, Gilbert, AZ (speaker for off label uses of Wellbutrin SR/ Lamictal); Jeff Green, MD, Princeton, NJ (speaker for off label uses of Wellbutrin SR/ Lamictal); Sidney Zisook, MD, La Jolla, CA.(Wellbutrin SR/Lamictal); Patricia Suppes, MD, San Antonio, TX (speaker for off label use of Lamictal). *7AC 0000685-705.*

2. Preceptorships

682. Preceptorships were a more subtle form of physician remuneration than payment for advisory boards or the purchase of large quantities of a physician's book.

683. The typical preceptorship involved a physician being compensated for permitting a GSK sales representative to trail the doctor during a certain medical procedure, or through the course of an entire day in a clinical setting. Each preceptorship was assigned a GSK prescription medication, similar to 'detailing.' For example, Greg Thorpe did a preceptorship with Colorado Springs neurologist Randall Bjork M.D., for which Dr. Bjork was compensated -- the ‘subject drug' for the preceptorship being GSK's migraine drug Imitrex.

684. Both Relator Thorpe and Relator Hamrick were assigned to a preceptorship with Barry A. Hendin, a neurologist in Phoenix, Arizona, with the subject of the preceptorship being

the drug Imitrex. Not only did Dr. Hendin prescribe GSK's drugs, but he served as a national speaker for GSK.

685. Relator Thorpe also did a short preceptorship with Tom Pence, D.O., an anesthesiologist at Memorial Hospital in Colorado Springs, for one full day, which involved knee replacement surgery, and the subject of which was the marketing of the GSK drugs Zofran for post operative nausea and vomiting, Zinacef for prevention of infection, and Zantac for prevention of acid reflux during and after surgery.

3. Entertainment

686. As alleged *supra*, GSK spent lavishly on sports and entertainment events for the purpose and intent of inducing physicians to prescribe GSK's drugs. Football and ice hockey games, theater, dinners, ski trips etc. were all part of GSK's marketing plan. Attached to the First Amended Complaint is a copy of the invoice for the 2001 Colorado Avalanche hockey play-offs in the amount of $23,600, indicating "sold to: Blair Hamrick, GlaxoSmithKline." *7AC 0000706.* These tickets were used to treat physicians to the hockey play-off games with the intent to influence them their prescription habits.

687. An example of the results achieved from offering this sort of remuneration is GSK's courting of Dr. Jeffrey Harazin, a psychiatrist from Colorado Springs, Colorado, for both indicated and off-label use of Wellbutrin SR and Lamictal, as memorialized in GSK sales rep contact reports:

- On 11/16/00 GSK sales representative Anne Cutter took Dr. Harazin's office to lunch, describing it as a "great detail," "wbsr [WellbutrinSR] comming [sic] around usining [sic] it for addiction, add, hyposex disorder as well aas [sic] depression.." The "great detail" in this context indicated some success in

convincing the physician to use the drug for off-label uses, including treatment of addiction, adult hyperactivity disorder, and hyposexual disorder.

- On 1/08/01, another GSK representative detailed Dr. Harazin, reminding him that approval Lamictal for treatment of bipolar disorder was “on its way.”
- On 6/08/01, GSK sales representative Anne Cutter detailed Dr. Harazin and reported that he "loved the avs game was impressed with glaxo motivated to write wbsr."
- On 10/11/01, GSK sales representative Ron Crews detailed Dr. Harazin for WellbutrinSR and reported "we went over new weight data" (GSK data indicating effectiveness of WellbutrinSR for off label treatment of comorbid obesity).
- On 5/08/02, a GSK sales representative detailed Dr. Harazin on Wellbutrin and Lamictaland "showed him weight loss data and anx vs zolo. [Zoloft, a competitive drug], he uses lamictal first line for bi-polar."
- On 7/17/02, another GSK sales representative detailed Dr. Harazin on WellbutrinSR and Lamictal and indicated "200 mg tabs [samples] and formulary avail. lamictal and fax back re rash."

4. Grand Rounds and Speaker Events

688. The performance evaluations of GSK's sales representatives rested largely upon the number of speaker events, grand rounds and entertainment events they could involve physicians in attending.

689. A "speaker program" would be attended by physicians recruited by GSK sales reps with promises of, at a minimum, fulfillment of CME requirements, along with meals,

entertainment and "medically related gifts." The speaker for the program would be expressly associated with a particular GSK prescription drug. Internal "Performance Review" documents demonstrate that GSK sales representatives were given high marks for setting up drug-specific speaker programs at which highly compensated physicians would promote GSK's drugs.

690. In his year 2000 performance review, for example, Blair Hamrick, was commended by GSK for "setting up Relenza speaker programs. His teamwork in Colorado Springs was able to produce a speakers program attended by 152 physicians for Relenza." Mr. Hamrick received an "Exceeded" rating based upon his ability to set up complementary entertainment and "educational" activities for physicians designed to induce them to prescribe specific GSK products. Mr. Hamrick's performance review specifically complimented him for the following activities:

- "3/29 Ceftin Grand Rounds Aurora Press Hospital, Dr. Mostow"
- "5/7 Valtrex Grand Rounds Aurora Pres Hospital, Dr. McGregor"
- "8/21 Wellbutrin Program Elitch Gardens, Dr. Alston" [Amusement Park Event]
- "8/30 Ceftin Grand Rounds Aurora Press Hospital, Dr. Mostow"
- "9/13 Relenza Program Broncos Game Dr. Lalazari" [Professional Football Game]
- "12/3 Relenza Grand Rounds Aurora Press Hospital Dr. Mostow"
- "12/13 IBS Program Denver Health Center Dr. Hanna"
- "12/16 Relenza Program Broadmore [sic] Dr. Nathan" [Health spa]

691. The commercial purpose of flying a GSK speaker physician in to do grand rounds at a hospital was made clear to the speaker as well as the GSK sales representative, but was not always appreciated by the host hospital.

692. On 9/13/99 Blair Hamrick arranged for GSK to fly Dr. Jacob Lazari in from San Francisco to do two talks to physicians at a Denver Bronco's game, but because of logistical problems, he never spoke. However, the following day, on 9/14/99, Dr. Lazari led a Grand Rounds at Rose Hospital in Denver, Colorado that was so obviously a marketing ploy for GSK's products (in this case Relenza,) that Dr. Kenneth A. Lichtenstein of Rose Hospital chastised Hamrick and told him that "Grand Rounds was not supposed to be a commercial." Although some of GSK's national speakers were willing to travel to another state for just one engagement, others required more: Neil Berliner, M.D., from Flushing, N.Y., for example, required that there be a minimum of 6 lectures at $2000 per lecture, in addition to all meals, lodging and travel expenses.

5. Lunch For Physicians' Offices

693. The custom of pharmaceutical sales representatives taking physicians to lunch or bringing them lunch to attempt to sell their company's products has been a commonly accepted practice in the pharmaceutical industry; however, GSK, during the period alleged in this amended complaint, took this practice to extremes in order to attempt to influence physicians to prescribe its products, spending lavishly to treat entire medical clinics to lunch in order to influence just a handful of physicians.

694. In one month alone, April, 2001, Relator Greg Thorpe treated 55 people from ExpressCare on April 3 in order to access three doctors at the clinic, 30 people from Dr. Paaps's office on April 10 to access 2 physicians, 12 people at Dr. O'Donnell's office on April 12 to see one physician, 20 people at Dr. Ravins's office on April 18 to see 2 doctors, 10 people at Dr. McMahon's office on April 19 to access just one physician, 10 people at Dr. Shingledecker's office on April 24 (when the physician did not show up), and half a dozen people on April 26 -

along with a payment of $1,000 to local neurologist Dr. Fodor - to give a presentation to the other physicians attending during the lunch. Such expenditures were not uncommon for GSK sales representatives.

6. Hunting, Fishing, Skiing and Golf Outings

695. Individual physicians were often treated by GSK sales representatives to the sporting activity of their choice. For example, relator Greg Thorpe treated psychiatrist Richard Marciniak, groomed to be a local ‘thought leader' for Wellbutrin and Lamictal, on numerous hunting trips; GSK sales representative Ron Crews took Air Force Academy neurologist Joseph Clark, M.D. on numerous fishing trips as well as to hockey games and used him frequently as a local speaker for GSK's migraine medication Imitrex.

696. GSK District Sales Manager Pat Keith, at a regional meeting of GSK's sales representatives at the Inverness hotel and conference center in Colorado on February of 2001, encouraged representatives to spend lavishly on doctors by taking them skiing, to sports events, theater and dinner. Keith at that time handed to all of the sales representatives a document entitled "Ideas for Setting up Programs" that listed theaters, ballet, opera, orchestra, and day-spa meetings, along with telephone numbers for the various venues. Also suggested were such activities as golf tournaments, fly fishing, "cooking class, pheasant shoot and clay shooting."

7. Seeding Trials

697. GSK, at all times relevant to this Seventh Amended Complaint, and on an ongoing basis, has used programs throughout the United States that GSK calls “Seeding Trials.” Seeding trials are essentially mini studies funded by GSK and conducted by top prescribing physicians of GSK products.

698. Thousands of physicians have participated in these programs. Physicians are recruited either by sales representatives or “Market Development" managers from the marketing department for each GSK drug.

699. Seeding trials are designed by marketing to appear “scientific,” but primarily are done only to benefit sales of GSK drugs. It is also deceiving to patients who participate and may be put on a lifetime therapy only because their physician was paid to put them on the drug.

700. In reality, the so called “seeding trials” are bribes GSK pays to physicians to prescribe GSK drugs to their patients.

701. Pursuant to the seeding trials, physicians are paid generous fees for the little work that is normally needed to conduct the "trial." Of note, the seeding trials typically involve on-label uses of the drugs.

702. Relators are of the belief and opinion that GSK sponsored seeding trials for most if not all of the drugs identified in this complaint.

703. Normally only high prescribing physicians were selected for these programs, as the results would be twofold:

A. The physician would have put the patient on the drug, and many of the drugs used would be “lifetime drugs,” defined below. These physicians typically had more patients to work with, and could evaluate multiple drugs.

B. Since these physicians used the drugs in “seeding trials,” even after the trial period was over, which was normally a short period time 4-12 weeks depending on the drug, the physician would be more likely to use the drug in the future. The goal was to get the physicians familiar with the drug, so in the future, the “high prescribers,” would have ultimately many other patients to put on the drug.

704. Most of the drugs used in the seeding trials, including Imitrex, Wellbutrin SR, Lotronex, Valtrex and Advair, were drugs that would be considered "lifetime drugs." In other words, they are drugs patients would be prescribed for the duration of their lives because the

underlying conditions are not "curable" and instead are managed with medication. GSK would increase sales and market share of the drugs which were the *quid pro quo* for providing samples and paying physicians to do the “studies.”

705. Physicians were paid a generous fee for each patient enrolled in the seeding trial. The payments typically ranged from $1,000-$3,000 per patient. Moreover, each trial had its minimum patient enrollment threshold to qualify as a seeding trial. Usually, there was a 30 patient threshold, and at most times there was an at least 5 patient enrollment requirement.

706. After the “trial period," a physician would merely fill out a short, one or two page form-describing the results obtained and any adverse events. Physicians were likely to omit or downplay adverse events, because they may put their future relationship with GSK in jeopardy, if they overstated side effects, non-compliance, or lack of efficacy.

707. Many of the some 49,000 speakers for GSK who participated in these “trials,” then could talk to their colleagues about the drugs they “tested.” Some physicians, whether they be family practitioners, such as Jay Adler M.D., Colorado Springs, CO, or specialists like Robert Nathan, also of Colorado Springs, would ultimately actually hire an entire staff and claim it was a “research arm” of their practice, reaping in huge amounts of money on a yearly basis.

708. In short, GSK's seeding trials involved the funneling of hundreds of millions of dollars to physicians in exchange for prescribing GSK drugs on a nationwide basis under the guise of being a study.

709. Two examples of Seeding Trials for Advair known by Relator Hamrick include those run by Colorado Asthma and Allergy and National Jewish Hospital in Denver, Colorado. Relator Hamrick also recalls that Pulmonologists were also common participants in Advair Seeding Trials.

8. Samples

710. Another common practice in the pharmaceutical industry, the distribution of free samples by pharmaceutical companies to physicians, was also systematically abused by GSK during the period alleged in this amended complaint.

711. GSK sales representatives were encouraged to distribute samples of medications to physicians for the physician's personal use, including off-label uses, in order to encourage physicians to prescribe GSK's medications.

712. GSK evaluated sample distribution in terms of 'return on investment.' For example, relator Blair Hamrick received commendation in his 10/08/03 Field Coaching Report from District Manager Ned Schneidewinde: "You use your GSK search data very well to help you and your teammates target the appropriate doctors to get the best ROI [‘Return on Investment'] time and samples."

713. Extremely disturbing was the practice of distributing expired product samples. It was common throughout the United States, that expired samples, samples abandoned for long periods in garages, and samples that had been left in car trunks for weeks or months at a time when temperatures inside the trunks could exceed 130 degrees Fahrenheit or dip below 20 degrees were distributed to Medicaid facilities and community health centers.

714. When dropping off the samples, sales representatives were told to say that the drugs would "probably be good up to two years past the expiration date." However, the GSK knew that the improper storage of GSK drugs materially compromised the potency and or safety of the samples and samples. GSK engaged in this practice to avoid the high cost of shipping the samples back to the company for destruction.

715. Samples were also specifically utilized to promote Wellbutrin for off-label treatment of smoking cessation. When GSK's smoking cessation medication, Zyban, came under attack in mid-2001 in the United Kingdom from an unusually large number of adverse injury reports. GSK distributed to relator Greg Thorpe and other GKS sales representatives 'target lists' indicating high decile Zyban prescribing physicians while at the same time doubling samples of Wellbutrin and ceasing to distribute samples of Zyban. Since the two drugs were made up of the same basic chemical component, Bupropion Hydrochloride, sales representatives were expected to leave the Wellbutrin samples with physicians for use in smoking cessation.

716. Another example of GSK's misuse of samples was its intentional distribution of most of its Lamictal samples to psychiatrists, not to neurologists, at a time when the drug was only approved for the treatment of seizures, a disease state treated only by neurologists.

717. GSK has made efforts to conceal its activities in violation of the anti-kickback statute and the law relating to off-label marketing. To that end, GSK was notified of an investigation by the Justice Department into its marketing activities in the summer of 2003. Subsequently, on September 15, 2003, a memorandum was mailed out "To: U.S. Pharma Sales Force" stating "[S]everal of the GSK mail servers that support the field are running out of space. Some of them are close to capacity and may disrupt field e-mail service. We have identified and contacted users with the largest files but your additional action would also alleviate the situation. Please take action. Please delete as much e-mail as you can in order to maintain the stability of the field force e-mail servers."

718. Although GSK later issued a modification of this order on September 28, 2003 stating that documents subject to litigation holds or other legal or regulatory requirements mandating retention must be retained, the original memorandum resulted in the deletion of

thousands of emails. Also during this period, on September 19, 2003, at a meeting of regional sales representatives in Las Vegas, Nevada, a Market Development Manager named John Foy, made the rounds to each District room in the Region with the verbal message to all of the marketing representatives that "[I]f anybody has any power point speaker slides in their computers they should immediately be deleted/destroyed upon return home."

719. At a national meeting in Dallas, Texas, on March 17, 2004, GSK introduced what it called the "Write Right" program, changing the ways that sales representatives maintained their records. During that meeting a GSK attorney cautioned sales representatives about what events should or should not be recorded by using the example of "taking a physician to the Superbowl...is that something that we really want to document?" In the promotional brochure for the “Write Right” program, the first bullet point under “Rules for Accurate Writing” was the admonition “nothing is guaranteed to be confidential.”

720. Consistent with its other illegal marketing practices, GSK would often issue a disclaimer statement in its instructions to its sales representatives relating to anti-kickback activities. An example is the "Best Practices" booklet entitled "Optimizing Customer Focus Opportunities," distributed to sales staff in early 2002. On one page of this booklet, GSK states that it, unlike other pharmaceutical companies, chooses its programs for their educational content rather than the choice of venue ["Description of Best Practice: Industry has flooded physicians calendar's [sic] with educational opportunities at the finest restaurants and entertainment venues....Physicians have grown accustomed to selecting the educational topic based on the venue vs. the educational opportunity. Instead of focusing on trying to ‘top' our competitor venue we have focused on the educational opportunity for the customer."] but on the very next page, as an example of a "Best Practice," is attendance at a New England Patriots game where the

physicians actually get the honor of attending the pre-game warm up: "Description of Best Practice: Prior to a New England Patriot football game. Doctors hear a lecture on our products then 1 hour before the Sunday football game we go down to the field where we actually go on the field to watch pre-game warm-ups as well as player introductions."

B. GSK's Use of Medical Education Programs To Promote Off-Label Uses Of Its Medications In Violation Of The False Claims Act

721. During the period alleged in this complaint, GSK has paid significant remuneration to health care practitioners throughout the United States with the intent to cause the submission of false claims to Medicaid and Tricare/Champus as well as other federal health care programs. The methods of payment have included payment for honorariums, preceptorships, participation on advisory boards, lecturing to other physicians, promotion of book sales to encourage off label prescribing, as well as sponsorship of physicians to various entertainment, meals and luxury items.

722. Internal GSK documents reveal that GSK reaped a significant "return on investment" out of what it called "peer-to-peer" programs, essentially the hiring of health care practitioners involved in similar practices speaking to other health care practitioners about the efficacy of using GSK prescription medications for certain therapeutic uses, including off label uses. The effectiveness of paying physicians to network and to speak with other physicians concerning the off-label uses of GSK prescription medications is acknowledged in countless e-mails, voice mails and memoranda from GSK's regional supervisors to its sales force. The practice, begun in the early 1990's has continued through the date of this filing.

723. By way of example, in a memorandum dated January 28, 2003 from District Manager Ned Schneidewind, copied to Fred Gregg, Schneidewind extolled his sales force for their paid physician speaker programs and the impact those programs have had on the selling of

the drug Advair[8] by stating "Do peer to peer programs work? The numbers above support that they do." The e-mail goes on to list numerous CME, lunch and grand round programs at various places that were planned for the Colorado region. The success of these programs was evidenced in the world wide sales of prescription drugs such as Advair, which enjoyed sales of more than 1.5 billions dollars its first year on the market and outsold its diehard competitor Singulair in only its second year, despite its not having been approved for use in the treatment of Chronic Obstructive Lung Disease at that point in time.

724. GSK carefully tracks return on investment data for its CME programs throughout the course of its various programs that promote drugs such as Advair and Wellbutrin off-label. Blair Hamrick was given this information by one Michelle Ludekie, an Asthma Care Network[9] Representative, who along with her manager had lunch with Hamrick on October 1, 2003 and informed him that "[W]e are not supposed to tell you about this, but the company has done some return on investment studies on our education program, and they found out that for every doctor that completes the [CME] program, they average 2 extra prescriptions of Advair per week."

725. GSK cuts grants and preceptorships for physicians and clinics that do not prescribe GSK drugs. When Blair Hamrick was ordered to spend a day trailing his Regional[10] Vice President Fred Gregg on October 10, 2002, the two made a call upon "Colorado Allergy and Asthma Centers, P.C." Both before and after the meeting with the physicians at this clinic Gregg informed Hamrick that "[W]e are as a district going to stop calling on these people, because we have given them a bunch of money, but they still don't write a high enough

[8]"According to the SPP data 3 months NRx on Advair this November is 4.7%. West Denver is 2.7% and Boulder is 2%."

[9]A so-called 'independent contractor' utilized by GSK to provide CME's to physicians, the network at this time did not work for other drug companies.

[10]The Western Region comprises all of the Western states with the exception of California, including Washington, Oregon, Nevada, Arizona, Colorado, Wyoming, Idaho and Montana.

percentage of Advair...if they won't help us, then screw them we won't be supporting any more of their funding requests." During the following years, this particular group regained GSK's confidence by writing more prescriptions of Advair, Flovent, Serevent, and other GSK products, even going so far as to post its own commercialized message in favor of Advair and Serevent on its web page (authored by member Dr. Jerold Koepke), defending the GSK drug Serevent at a time when it was under increasing attack for deaths caused by use of the drug and recommending use of the drug Advair, and despite the fact that a U. S. clinical trial of Serevent, a component of Advair, had been halted in January of 2003 due to a number of life-threatening events.

726. GSK also dropped physicians as speakers when the records disclosed that the physicians did not prescribe enough GSK prescription medications. Colorado Springs physician Dr. Patricia Fodor was targeted by GSK, taken by sales representative Anne Cutter to a high priced spa in Colorado Springs, and was being groomed by GSK to be a speaker and thought leader. Although she was not a particularly effective speaker, she was targeted by GSK because she was prescribing competitive prescription medications such as Maxalt and Zomig. However, after it became apparent through GSK's tracking records that Dr. Fodor continued to write prescriptions for Merck and failed to write enough prescriptions for GSK, Greg Thorpe's supervisor, Pat Keith, instructed both Thorpe and Hamrick to drop her from the speaker list.

727. GSK's internal documents reveal that GSK's medical education programs for physicians and other health care providers were intended as a financial investment and directed at high decile prescribers. For that reason GSK made a concerted effort to record the names and other identifying information of attendees.

728. In a March 15, 2002 note from Mark B. Schwartz, Senior Market Development Manager for GSK CNS (Central Nervous System) Division, forwarding an e-mail from Sales

District Manager Daniel Romero to U. S. Marketing Development Managers and Sales Managers, GSK states "in order to achieve maximum ROI [Return on Investment] with the FIRST program [GSK's promotional program involving free CME seminars dealing with its Imitrex product], we have to first make sure that our representatives are recruiting high decile customers" and in order to accomplish this task, it was "most important" to record the physicians' correctly spelled name, address, specialty and "most importantly - ME#'s" - indicating the Medical Education number that would identify the doctor as having attended the program. *7AC 0000684*. This information would then be utilized by GSK to track the attendee's prescribing records.

729. Internal documents explicitly and clearly confirm that "peer-to-peer" meetings, CME's and speaker engagements were primarily for a commercial rather than an educational purpose. Specifically, an internal document issued to GSK sales representatives nationwide in July of 2002 indicated that the "Medical Services" program "is committed to leveraging science for patients and commercial success..." and that "[O]ur proactive activities are primarily targeted at: Key Opinion Leader (KOI) influence and development...[O]ur goal is to support additional regional activities (speaker programs, group presentations, roundtable discussions) that are commercially important." The document, issued in 2001, specifically explained how GSK representatives may direct physicians to "Regional Medical Scientists" in order to get answers to questions that could be "commercially important." Regional Medical Scientists were GSK employees with M.D., Ph.D. or PharmD. Degrees utilized to "enhance customer focus by providing medical information, support activities, and programs that help optimize the utilization of GSK products."

730. GSK also utilized documents from its CME programs that demonstrated that off-label discussions at CMEs influenced the thinking of attendees about the uses of its prescription mediations. In a nationwide seminar called "Understanding Depression: Matching the Neurotransmitter to the Patient" held in Denver, Colorado on April 13, 2002, GSK recorded responses to the seminar that indicated that it was successful in encouraging increased prescription of Wellbutrin both for its legal indication as well as its off-label uses, including responses such as "Use of Bupropion SR as augmentive therapy or with mixed type of depression - Pam Graham, MHS, PA-C;" "Use more Wellbutrin - Annette Pereceful, ANP"; "Consider adding Bupropion to certain Patients - Elizabeth Fries, PA-C"; "Use Wellbutrin in addition to SSRI's."

731. Even before Advair received its first indication for the treatment of asthma in adults in August of 2000, GSK embarked upon an aggressive marketing campaign that it called "Turning America Purple," expending enormous resources training its sales representatives in both on-label and off-label uses of the drug, paying physicians to give lectures and 'peer-to-peer' programs as 'thought leaders,' and giving influential physicians grants and preceptorships to help promote Advair for off-label as well as on-label uses. The program was successful in boosting over-all sales of Advair, with world-wide sales exceeding 4 billion dollars by year 2003.

C. GSK Targeted Medicaid And Tricare/CHAMPUS With Off-Label Marketing Of Its Prescription Medications In Violation Of The Anti-Kickback Statute

732. During the period alleged in this Amended Complaint and continuing to the present time, GSK has compiled statistics on physicians with the highest prescribing rates for Medicaid reimbursement of their prescription drug products and made this information available

to their sales force so that sales representatives could more efficiently direct their illegal compensatory and off-label marketing activities.

733. As described above, GSK's sales representatives for the Western Region were instructed to carry a laminated card with them at all times that served as a constant reminder for sales representatives to "[E]xploit the bolus" of government-funded healthcare programs including Medicaid and Tricare in marketing GSk drugs.

734. GSK's sales representatives were also provided with bookmarks to take with them to physician offices and place on appropriate samples of GSK medications indicating that the drug was "Available on Medicaid."

735. In addition to the Medicaid sales aids, sales representatives were explicitly informed that Medicaid targeting was the key to a successful region. Specifically, at the Western Regional Meeting held in Orlando, Florida in February 2003, Regional Manager Fred Gregg presented a power point presentation to the GSK sales representatives in attendance which informed them that California was #1 in the Region because of Medicaid targeting and that "Targeting Key Medicaid Physicians is a No-Brainer."

736. The emphasis to target Medicaid providers was also routinely noted on Field Contact Reports which were essentially report cards completed by senior management following ride alongs. Namely, in May, August, and October 1998, Relator Hamrick was specifically instructed to "target high Medicaid and cash paying doctors." Such comments are indicative of the pervasive nature of Medicaid targeting within GSK.

737. GSK also provided its sales force with statistical data relating to specific prescribing physicians and their level of Medicaid prescriptions for specific GSK drugs. Included in these reports was the number of times each physician had been detailed by a GSK sales rep.

738. Significantly, the data GSK reported to its sales representatives often included physicians with specialty areas that could only lead to Medicaid's paying for "off-label" uses. For example, the Imitrex Medicaid Target list, *7AC 0000411-0000412,* and distributed to GSK's sales representatives in the southern Colorado region, contains Medicaid prescribing data for pediatric neurologists Brian Grabert and Robin Morgan and pediatrician Richard Kouri, whose percentage of triptan prescriptions written for Imitrex on Medicaid accounts were 85.3%, 100% and 44% respectively. Relators Hamrick and Thorpe witnessed the fact that high decile Medicaid writers would receive greater compensation from sales representatives in the form of free dinners, sporting and entertainment events.

739. Similarly, the "Medicaid Targeting Data" distributed to GSK sales representatives for GSK's product Wellbutrin on July 20, 2002 (and attached to the First Amended Complaint as Exhibit #2), contains data indicating that the second highest Medicaid prescriber for Wellbutrin was pediatric psychiatrist Fred Michel, who, as indicated previously in this Amended Complaint, was paid by GSK to lecture to other physicians on the efficacy of Wellbutrin for pediatric uses, which were not approved by the FDA.

740. In addition to its Medicaid specific lists, GSK also distributed "Target Lists" of physicians relating to various other prescription plans including the following:

- Plan by Prescriber (November 15, 2000). *7AC 0000707-0000713.*

As well as data for physician prescriptions of other GSK products and data relating to certain physician specialties:

- Top Western Region Anti-Herpetic Writers (January 2002). *7AC 0000714-0000717*;

- Top 150 Depression Writers, Western Region (January 2002). *7AC 0000718-0000721*;
- Top 150 Neurologists for the Western Region (January 2002). *7AC 0000722-0000725*;
- Top 150 Migraine Prescribers for the Western Region (January 2002). *7AC 0000726-0000729*;
- Top "150 Psyches" for the Western Region (January 2002). *7AC 0000730-0000733*;
- Childhood Asthma Target List. *7AC 0000734-0000740.*

741. In addition to access to the Medicaid "target" lists for high Medicaid prescribing physicians, GSK sales representatives also had ‘quick access' to high decile Medicaid prescribers utilizing the nationwide software system on their company-issued notebook computers.

742. In fact, the following voice mail was left in March of 2004 for GSK sales representatives in the Western Region regarding the Medicaid information available on their computers:

> "This is a ‘best practice' I'm going to forward on to the region from one of our representatives in the Nebraska market place, and this message centers around identifying physicians with Medicaid as part of their practice. Now also I know that the [inaudible] affairs people have provided target lists through us as well but this is a great story from Theresa Gregg [a GSK marketing employee] on how to find this information out yourself in your territory. So here's the message and let’s talk to Medicaid physicians with a positive message on our products...[.from Theresa Gregg]: This is Theresa, Hey I just found a quick and easy way to figure out who our top Medicaid writers are and get those in descending order so I thought I would share that with you and if you feel like passing that on to the district, anybody who is looking for their Medicaid numbers

> if they go to first report, click on managed care then click on prescriber by plan reports and once you get to that window you want to click on search for Medicaid and the one you want to highlight and put on the right hand column is Medicaid and then in parentheses it says 'plan.' And then at the bottom you've got a choice of sort by prescriber or current three months, click on current three months and you'll get the Medicaid writers in descending order from highest to lowest and then just generate report, and you'll have all the information you need. So I hope this is helpful."

743. GSK's sales practices, combined with their frequent detailing, and use of physician 'peer-to peer' meetings, 'local thought leaders', and national speakers, helped the company convince high Medicaid prescribers to prescribe GSK products for off-label uses.

XV. DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relators Thorpe and Hamrick hereby demand a trial by jury.

XVI. CLAIMS FOR RELIEF

COUNT ONE
Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(1)[11]
Presenting or Causing to be Presented False Claims

744. Plaintiffs Thorpe, Hamrick and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

745. This is a *qui tam* action brought by Thorpe and Hamrick and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

746. The Federal False Claims Act, 31 U.S.C. §3729(a)(1) provides:

[11] 31 U.S.C. §3729(a)(1) has been amended and renumbered and is now styled as 31 U.S.C. 3729(a)(1)(A). To the extent that the new language of the amended statute is not retroactive, Plaintiffs assert that any and all false claims submitted after the enactment of the Fraud Enforcement and Recovery Act are deemed to be violations of the FCA, as amended.

> Liability for certain acts. Any person who--
>
> (A) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval
>
> *Id.*

747. By virtue of the above-described acts, among others, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval, and possibly continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States, in violation of 27 U.S.C. §3729(a)(1).

748. For example, those false claims include claims for reimbursement for off-label/non-medically accepted prescriptions of Defendants' drugs which would not have been submitted, and thereafter paid by the United States, but for the illegal practices of Defendants described in this Seventh Amended Complaint.

749. In addition, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with the Anti-Kickback Statute is a condition precedent for reimbursement under the Medicaid, Medicare and other federally-funded health programs. In other words, claims arising from an unlawful exchange violative of the Anti-Kickback Statute are, as a matter of law, ineligible for reimbursement and upon submission are false claims subject to the provisions of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*

750. By engaging in the fraudulent and illegal practices described herein, Defendants violated the Anti-Kickback Statute, and in turn caused false claims to be submitted in violation of the Federal False Claims Act, §3729(a)(1). Specifically, Defendants' material violations of the Anti-Kickback Statute lead to the submission of claims for Defendants drugs to the United States. Those claims were false, as they were ineligible for reimbursement, and therefore by submitting or causing these false claims to be submitted, Defendants further violated 31 U.S.C. §3729(a)(1) from at least 1997 to the present.

751. Plaintiff United States, unaware of the falsity of the claims that the Defendants caused doctors, pharmacies hospitals and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid said doctors, hospitals, pharmacies and other health care providers for claims that would otherwise not have been allowed. These claims – prescription drug reimbursement claims for Defendants' drugs – were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

752. For those claims that Defendants submitted or caused to be submitted, it was foreseeable and in fact the intended result that those claims would be submitted. Further, at all times relevant to the Complaint Defendants acted with the requisite scienter.

753. By reason of Defendants' unlawful practices, substantial numbers of doctors, hospitals, pharmacies and other health care providers in the United States have been induced to purchase substantial quantities of Defendants' drugs and these practices thus provided substantial profits to Defendants.

754. By reason of these unlawful practices by Defendants, as aforesaid, doctors, hospitals, pharmacies and other health care providers have been induced to purchase Defendants'

drugs rather than recommending less expensive procedures or treatment options for their patients.

755. The amounts of the false or fraudulent claims to the United States were material. Plaintiff United States, being unaware of the falsity of the claims and/or statements caused to be made by Defendants, and in reliance on the accuracy thereof paid and continues to pay for Defendants' unlawfully induced prescriptions.

756. It is believed that as a result of Defendants' violations of 27 U.S.C. § 3729(a)(1), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars, and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim presented or caused to be presented by Defendants.

757. Thorpe and Hamrick are private persons with direct and independent knowledge of the allegations of this Seventh Amended Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of themselves and the United States.

COUNT TWO
Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(2)[12]
Creation or Use of False Statements or Records Material to a False Claim

758. Plaintiffs Thorpe and Hamrick and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

759. This is a *qui tam* action brought by Thorpe and Hamrick and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

[12] 31 U.S.C. §3729(a)(2) has been amended and renumbered and is now styled as 31 U.S.C. 3729(a)(1)(B). To the extent that the new language of the amended statute is not retroactive, Plaintiffs assert that any and all false claims submitted after the enactment of the Fraud Enforcement and Recovery Act are deemed to be violations of the FCA, as amended.

760. The Federal False Claims Act, 31 U.S.C. §3729(a)(2) provides:

Liability for certain acts. Any person who--

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid

Id.

761. By virtue of the above-described acts, among others, Defendants knowingly made used or caused to be made or used false records or statements to get false claims paid by the United States, and possibly continues to do so, in violation of 27 U.S.C. §3729(a)(2).

762. For example, claims for reimbursement for off-label prescriptions of Defendants' drugs would not have been submitted, and thereafter paid by the United States, but for the illegal practices of Defendants described in this Seventh Amended Complaint including their false records and statements.

763. In addition, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with the Anti-Kickback Statute is a condition precedent for reimbursement under the Medicaid, Medicare and other federally-funded health programs. The claims Defendants submitted or caused to be submitted failed to disclose the underlying violation of the Anti-Kickback Statute and/or affirmatively misrepresented that the clams were made in compliance with all applicable laws including the Anti-Kickback Statute.

764. By engaging in the fraudulent and illegal practices described herein, Defendants violated the Anti-Kickback Statute. Defendants' material violations of the Anti-Kickback Statute lead to the submission of claims for Defendants drugs to the United States. Those claims

were false, as they were ineligible for reimbursement, and by making or causing to be made false records or statements to get those false claims paid, Defendants further violated 31 U.S.C. §3729(a)(2) from at least 1996 to the present.

765. Plaintiff United States, unaware of the falsity of the records and/or statements which the Defendants made or caused doctors, pharmacies hospitals and other health care providers to make to get false claims paid, and in reliance on the accuracy thereof, paid said doctors, hospitals, pharmacies and other health care providers for claims that would otherwise not have been allowed. These claims – prescription drug reimbursement claims for Defendants' drugs – were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

766. For those records and/or statements that Defendants made or used or caused to be made or used, it was foreseeable and in fact the intended result that those statements and/or records would result in the payment of false reimbursement claims for Defendants' drugs. Further, at all times relevant hereto, Defendants acted with the requisite scienter.

767. By reason of Defendants' unlawful practices, as aforesaid, substantial numbers of doctors, hospitals, pharmacies and other health care providers in the United States have been induced to prescribe and purchase substantial quantities of Defendants' drugs and thus provided substantial profits to Defendants. Moreover these purchases of Defendants drugs occurred rather than purchases of less expensive procedures or treatment options for patients.

768. The amounts of the false or fraudulent claims caused to be paid pursuant to Defendants' false records and statements made or used or caused to be made or used to the United States were material. Plaintiff United States, being unaware of the falsity of the records

and/or statements made or caused to be made by Defendants, and in reliance on the accuracy thereof, paid claims that Defendants knew to be false, as they intended.

769. It is believed that as a result of Defendants' violations of 27 U.S.C. §3729 (a)(2), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars, and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendants.

770. Thorpe and Hamrick are private persons with direct and independent knowledge of the allegations of this Seventh Amended Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of themselves and the United States.

COUNT THREE
Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(3)[13]
Conspiracy

771. Plaintiffs Thorpe and Hamrick and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

772. This is a *qui tam* action brought by Thorpe and Hamrick and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

773. The Federal False Claims Act, 31 U.S.C. §3729(a)(1)(C) provides:

> Liability for certain acts. Any person who—
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); …is liable to the United States Government for a civil penalty of not less

[13] 31 U.S.C. §3729(a)(3) has been amended and renumbered and is now styled as 31 U.S.C. 3729(a)(1)(C). To the extent that the new language of the amended statute is not retroactive, Plaintiffs assert that any and all false claims submitted after the enactment of the Fraud Enforcement and Recovery Act are deemed to be violations of the FCA, as amended.

> than $ 5,500 and not more than $11,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, … *Id.*

774. In violation of 31 U.S.C. §3729(a)(3), by the foregoing acts and omissions, Defendant Defendants conspired with physicians, paid consultants and others including but not limited to those physicians identified in this complaint to defraud the United States by getting false and fraudulent claims paid and approved in violation of the False Claims Act, 31 U.S.C. §3729(a)(3).

775. By the foregoing acts and omissions, Defendants took actions in furtherance of their conspiracies, including but not limited to the payment of substantial sums of monies and/or illegal kickbacks to its co-conspirators as well as entering into unlawful contracts. Indeed, Defendants conspired to violate the AKS by unlawfully offering incentives to physicians and offering or receiving incentives from others that were in a position of authority to cause other physicians to write unnecessary prescriptions of Defendants drugs, including for off-label uses. Said actions constitute violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(3). Defendants committed other overt acts set forth above in furtherance of that conspiracy, all in violation of the laws of and causing damage to the United States.

776. As a consequence of Defendants' violations of 27 U.S.C. §3729 (a)(3), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars, and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim Defendants conspired to get paid or allowed.

777. Thorpe and Hamrick are private persons with direct and independent knowledge of the allegations of this Seventh Amended Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of themselves and the United States.

COUNT FOUR
Unlawful Retaliation Against Relator Greg Thorpe
In Violation of 31 U.S.C. § 3730(h)

778. Plaintiff Thorpe realleges and incorporates by reference each and every of the foregoing paragraphs as if fully set forth herein.

779. In violation of 31 U.S.C. § 3730(h), GSK retaliated against Thorpe because he engaged in conduct protected by the False Claims Act, as alleged in detail *supra*. GSK's retaliation included, but was not necessarily limited to, the following retaliatory actions:

a. GSK subjected Thorpe to retaliatory terms and conditions of employment, including without limitation subjecting his work to increased scrutiny; disciplining him without legitimate reason or basis; rejecting his requests that any record of said illegitimate discipline be removed from his personnel file; and placing him on administrative leave, also without legitimate reason or basis;

b. GSK terminated Thorpe's employment;

c. GSK substantially and materially breached the Settlement Agreement; and,

d. Subsequent to Thorpe's termination, and continuing to the present, GSK has had a direct and material role in causing Thorpe to become unemployable within the pharmaceutical industry.

780. As a direct and proximate result of GSK's unlawful actions complained of herein, Thorpe has suffered, and in the future will suffer, back pay and fringe benefit losses, front pay and fringe benefit losses, and other special losses comprised of in part, but not limited to: past and future job search costs, past and future unreimbursed medical and dental costs for his family and himself; unreimbursed moving expenses, and past and future cost of borrowing funds to meet financial obligations.

781. Thorpe is entitled to reinstatement with the same seniority status but for the retaliation, two times the amount of back pay losses he has incurred, interest on these back pay losses, damages sufficient to compensate him for all front pay and fringe benefit losses, as well as compensation for any special damages he has sustained as a result of the GSK' unlawful conduct.

782. Finally, Thorpe is also entitled to an award of all litigation costs and reasonable attorney's fees he has incurred in this action.

783. GSK substantially and materially breached the Settlement Agreement as set forth above, as a result of which the Settlement Agreement is rescinded and Thorpe is excused from any further performance of his obligations thereunder.

784. To the extent required by law, Thorpe tenders back any benefits received under the Settlement Agreement to which he would not otherwise have been entitled.

COUNT FIVE
Retaliatory Discharge of Relator Thorpe in Contravention of Public Policy

785. Plaintiff Thorpe realleges and incorporates by reference each and every of the foregoing paragraphs as if fully set forth herein.

786. When Thorpe undertook to expose and complain about acts and omissions on the part of GSK which were in violation of the False Claims Act, and when Thorpe refused to engage or participate in acts and omissions made unlawful by the False Claims Act, he was exercising his statutory rights, as well as vindicating the public policy, set forth in the False Claims Act.

787. Employers in Colorado have a duty not to discharge employees in retaliation for their having exercised their statutory rights and vindicated the public policy set forth in statutes such as the False Claims Act.

788. GSK materially breached this duty by terminating Thorpe's employment in retaliation for the fact that he exercised his statutory rights under and vindicated the public policy set forth in the False Claims Act, as alleged in detail *supra*.

789. GSK's retaliatory discharge of Thorpe was attended by circumstances of fraud, malice, and/or willful and wanton

790. As a direct and proximate result of GSK's decision to discharge Thorpe's employment in retaliation for his having engaged in conduct protected by the False Claims Act, Thorpe has suffered, and in the future will suffer, back pay and fringe benefit losses, front pay and fringe benefit losses, out-of-pocket pecuniary and other special losses, mental suffering, emotional distress, loss of enjoyment of life, humiliation, loss of professional reputation, intimidation and inconvenience, and other compensable, non-economic injuries.

791. Thorpe is entitled to all economic and non-economic damages necessary to make him whole and restore him to the economic\ and professional position he would have been in but for GSK's retaliatory discharge in contravention of public policy. Finally, Thorpe is also entitled to an award of punitive or exemplary damages as allowed by law, in an amount to be determined at trial.

COUNT SIX
Unlawful Retaliation Against Relator Blair Hamrick
In Violation of 31 U.S.C. § 3730(h)

792. Plaintiff Hamrick realleges and incorporates by reference each and every of the foregoing paragraphs as if fully set forth herein.

793. In violation of 31 U.S.C. § 3730(h), GSK retaliated against Hamrick because he engaged in conduct protected by the False Claims Act, as alleged in detail *supra*. GSK's retaliation included, but was not necessarily limited to, the following retaliatory actions:

a. GSK subjected Hamrick to retaliatory terms and conditions of employment, including without limitation subjecting his work to increased scrutiny; reprimanding him in front of colleagues and supervisors without legitimate reason or basis; and placing him on administrative leave, also without legitimate reason or basis;

b. GSK demoted Hamrick;

c. GSK terminated Hamrick's employment; and,

d. Subsequent to Hamrick's termination, and continuing to the present, GSK has had a direct and material role in causing Hamrick to become unemployable within the pharmaceutical industry.

794. As a direct and proximate result of GSK's unlawful actions complained of herein, Hamrick has suffered, and in the future will suffer, back pay and fringe benefit losses, front pay and fringe benefit losses, and other special losses comprised of in part, but not limited to: job search costs, unreimbursed medical and dental costs for his family and himself; moving expenses, tax penalties for early withdrawals from § 401K and cash balance plans, and past and future cost of borrowing funds to meet financial obligations.

795. Hamrick is entitled to reinstatement with the same seniority status but for the retaliation, two times the amount of back pay losses he has incurred, interest on these back pay losses, damages sufficient to compensate him for all front pay and fringe benefit losses, as well as compensation for any special damages he has sustained as a result of the GSK's unlawful conduct. Finally, Hamrick is also entitled to an award of all litigation costs and reasonable attorney's fees he has incurred in this action.

COUNT SEVEN
Retaliatory Discharge of Relator Hamrick In Contravention of Public Policy

796. Plaintiff Hamrick realleges and incorporates by reference each and every of the foregoing paragraphs as if fully set forth herein.

797. When Hamrick undertook to expose and complain about acts and omissions on the part of GSK which were in violation of the False Claims Act, and when Hamrick refused to engage or participate in acts and omissions made unlawful by the False Claims Act, he was exercising his statutory rights, as well as vindicating the public policy, set forth in the False Claims Act.

798. Employers in Colorado have a duty not to discharge employees in retaliation for their having exercised their statutory rights and vindicated the public policy set forth in statutes such as the False Claims Act.

799. GSK materially breached this duty by terminating Hamrick's employment in retaliation for the fact that he exercised his statutory rights under and vindicated the public policy set forth in the False Claims Act, as alleged in detail *supra*.

800. GSK's retaliatory discharge of Hamrick was attended by circumstances of fraud, malice, and/or willful and wanton conduct.

801. As a direct and proximate result of GSK's decision to discharge Hamrick's employment in retaliation for his having engaged in conduct protected by the False Claims Act, Hamrick has suffered, and in the future will suffer, back pay and fringe benefit losses, front pay and fringe benefit losses, out-of-pocket pecuniary and other special losses, mental suffering, emotional distress, loss of enjoyment of life, humiliation, loss of professional reputation, intimidation and inconvenience, and other compensable, non-economic injuries.

802. Hamrick is entitled to all economic and non-economic damages necessary to make him whole and restore him to the economic and professional position he would have been in but for GSK' his retaliatory discharge in contravention of public policy. Finally, Hamrick is also entitled to an award of punitive or exemplary damages as allowed by law, in an amount to be determined at trial.

COUNT EIGHT
California False Claims Act
Cal Gov't Code §12651(a)(1)-(3)

803. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

804. This is a claim for treble damages and penalties under the California False Claims Act.

805. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

806. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

807. By virtue of the acts described above, defendants conspired with each other and with others to defraud the California by inducing the California State Government to pay or approve false or fraudulent claims.

808. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

809. By reason of the defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

810. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT NINE
Connecticut False Claims Act
Chapter 319v, Sec. 17b-301 *et seq.*

811. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

812. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

813. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut Government for payment or approval.

814. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut Government to approve and pay such false and fraudulent claims.

815. By virtue of the acts described above, defendants conspired with each other and with others to defraud Rhode Island by inducing the Connecticut Government to pay or approve false or fraudulent claims.

816. The Connecticut Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

817. By reason of the defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

818. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TEN
Delaware False Claims And Reporting Act
6 Del C. §1201(a)(1)-(3)

819. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

820. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

821. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

822. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

823. By virtue of the acts described above, defendants conspired with each other and with others to defraud Delaware by inducing the Delaware State Government to pay or approve false or fraudulent claims.

824. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

825. By reason of the defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

826. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT ELEVEN
Florida False Claims Act
Fla. Stat. Ann. §68.082(2)

827. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein..

828. This is a claim for treble damages and penalties under the Florida False Claims Act.

829. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

830. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

831. By virtue of the acts described above, defendants conspired with each other and with others to defraud Florida by inducing the Florida State Government to pay or approve false or fraudulent claims.

832. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

833. By reason of the defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

834. The State of Florida is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWELVE
Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

835. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

836. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

837. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

838. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

839. By virtue of the acts described above, defendants conspired with each other and with others to defraud Hawaii by inducing the Hawaii State Government to pay or approve false or fraudulent claims.

840. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

841. By reason of the defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

842. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT THIRTEEN
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. §175/3(a)(1)-(3)

843. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

844. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

845. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

846. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

847. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

848. By virtue of the acts described above, defendants conspired with each other and with others to defraud Illinois by inducing the Illinois State Government to pay or approve false or fraudulent claims.

849. By reason of the defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

850. The State of Illinois is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT FOURTEEN
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(1)-(3)

851. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

852. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

853. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

854. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

855. By virtue of the acts described above, defendants conspired with each other and with others to defraud Massachusetts by inducing the Massachusetts State Government to pay or approve false or fraudulent claims.

856. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

857. By reason of the defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

858. The State of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT FIFTEEN
Nevada False Claims Act
Nev. Rev. Stat. Ann. §357.040(1)(a)-(c)

859. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

860. This is a claim for treble damages and penalties under the Nevada False Claims Act.

861. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

862. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

863. By virtue of the acts described above, defendants conspired with each other and with others to defraud Nevada by inducing the Nevada State Government to pay or approve false or fraudulent claims.

864. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

865. By reason of the defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

866. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT SIXTEEN
New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-14-1 et seq. and New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §44-9-1 et seq

867. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

868. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act.

869. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

870. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

871. By virtue of the acts described above, defendants conspired with each other and with others to defraud New Mexico by inducing the New Mexico State Government to pay or approve false or fraudulent claims.

872. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

873. By reason of the defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

874. The State of New Mexico is entitled to civil penalties for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT SEVENTEEN
North Carolina False Claims Act
N.C. Gen. Stat. §§1-605 *et seq.*

875. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

876. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

877. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

878. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

879. By virtue of the acts described above, Defendants conspired with each other and with others to defraud North Carolina by inducing the North Carolina State Government to pay or approve false or fraudulent claims.

880. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

881. By reason of the Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

882. The State of North Carolina is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT EIGHTEEN
Tennessee Medicaid False Claims Act
Tenn. Code Ann. §71-5-182(a)(1)

883. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

884. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Law.

885. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

886. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

887. By virtue of the acts described above, defendants conspired with each other and with others to defraud Tennessee by inducing the Tennessee State Government to pay or approve false or fraudulent claims.

888. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

889. By reason of the defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

890. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT NINETEEN
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §36.002

891. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

892. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

893. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

894. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

895. By virtue of the acts described above, defendants conspired with each other and with others to defraud Texas by inducing the Texas State Government to pay or approve false or fraudulent claims.

896. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

897. By reason of the defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

898. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWENTY
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(1)-(3)

899. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

900. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

901. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

902. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

903. By virtue of the acts described above, defendants conspired with each other and with others to defraud Virginia by inducing the Virginia State Government to pay or approve false or fraudulent claims.

904. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

905. By reason of the defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

906. The State of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWENTY-ONE
District of Columbia False Claims Act
D.C. Code Ann. § 2-308.14 (a)(1)-(3), (7)

907. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

908. This is a claim for treble damages and penalties under the District of Columbia False Claims Act.

909. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

910. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

911. By virtue of the acts described above, defendants conspired with each other and with others to defraud the District of Columbia by inducing the District of Columbia Government to pay or approve false or fraudulent claims.

912. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

913. By reason of the defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

914. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWENTY-TWO
Georgia False Medicaid Claims Act
O.C.G.A. §§ 49-4-168 et seq.

915. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

916. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.

917. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

918. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

919. By virtue of the acts described above, defendants conspired with each other and with others to defraud Georgia by inducing the Georgia State Government to pay or approve false or fraudulent claims.

920. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

921. By reason of the defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

922. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWENTY-THREE
Indiana False Claims and Whistleblower Protection Act
I.C. 5-11-5.5

923. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

924. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

925. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

926. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

927. By virtue of the acts described above, defendants conspired with each other and with others to defraud Indiana by inducing the Indiana State Government to pay or approve false or fraudulent claims.

928. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

929. By reason of the defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

930. The State of Indiana is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWENTY-FOUR
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §437 et. seq

931. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

932. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

933. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

934. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

935. By virtue of the acts described above, defendants conspired with each other and with others to defraud Louisiana by inducing the Louisiana State Government to pay or approve false or fraudulent claims.

936. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid

and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

937. By reason of the defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

938. The State of Louisiana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWENTY-FIVE
Michigan Medicaid False Claims Act
MCL 400.601-400.613

939. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

940. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

941. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

942. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

943. By virtue of the acts described above, defendants conspired with each other and with others to defraud Michigan by inducing the Michigan State Government to pay or approve false or fraudulent claims.

944. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

945. By reason of the defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

946. The State of Michigan is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWENTY-SIX
New York False Claims Act
N.Y. State Fin. §§ 187 et. seq.

947. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

948. This is a claim for treble damages and penalties under the New York State False Claims Act.

949. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

950. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

951. By virtue of the acts described above, defendants conspired with each other and with others to defraud New York by inducing the New York State Government to pay or approve false or fraudulent claims.

952. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

953. By reason of the defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

954. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWENTY-SEVEN
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §167:61-b(I)(a), (b), and (e)

955. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

956. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

957. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

958. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

959. By virtue of the acts described above, defendants conspired with each other and with others to defraud New Hampshire by inducing the New Hampshire State Government to pay or approve false or fraudulent claims.

960. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

961. .By reason of the defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

962. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWENTY-EIGHT
Oklahoma Medicaid False Claims Act
2007 OK. ALS 137

963. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

964. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

965. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

966. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

967. By virtue of the acts described above, defendants conspired with each other and with others to defraud Oklahoma by inducing the Oklahoma State Government to pay or approve false or fraudulent claims.

968. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

969. By reason of the defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

970. The State of Oklahoma is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWENTY-NINE
New Jersey False Claims Act
N.J. Stat. § 2A: 32C-1 et seq.

971. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

972. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

973. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

974. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

975. By virtue of the acts described above, defendants conspired with each other and with others to defraud New Jersey by inducing the New Jersey State Government to pay or approve false or fraudulent claims.

976. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

977. By reason of the defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

978. The State of New Jersey is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT THIRTY
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-1 *et seq.*

979. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

980. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

981. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

982. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

983. By virtue of the acts described above, defendants conspired with each other and with others to defraud Rhode Island by inducing the Rhode Island State Government to pay or approve false or fraudulent claims.

984. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

985. By reason of the defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

986. The State of Rhode Island is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT THIRTY-ONE
Wisconsin False Claims For Medical Assistance Act
Wis. Stat §20.931 et seq.

987. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

988. This is a claim for treble damages and penalties under the Wisconsin False Claims For Medical Assistance Act.

989. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

990. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

991. By virtue of the acts described above, defendants conspired with each other and with others to defraud Wisconsin by inducing the Wisconsin State Government to pay or approve false or fraudulent claims.

992. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

993. By reason of the defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

994. The State of Wisconsin is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT THIRTY-TWO
New York City False Claims Act
New York City Administrative Code §7-801-§7-810

995. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

996. This is a claim for treble damages and penalties against Defendants on behalf of the City of New York under the New York City False Claims Act, New York City Administrative Code §7-801-§7-810.

997. By virtue of the above-described acts, among others, Defendants knowingly and willfully promoted their drugs for non medically accepted uses.

998. By virtue of the above-described acts, Defendants knowingly made or caused to be made false claims for Defendants drugs to the New York City Government.

999. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York City Government to approve and pay such false and fraudulent claims.

1000. The New York City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

1001. By reason of the Defendant's unlawful acts, the City of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against defendant Defendants Inc. as follows:

a. That by reason of the aforementioned violations of the New York City False Claims Act provisions that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to not less than two times and not more than three times the amount of damages that the City of New York has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $15,000 for each violation of the New York City False Claims Act, New York City Administrative Code §7-801-§7-810;

b. That Relators, as *Qui Tam* Plaintiffs, be awarded the maximum amount allowed pursuant New York City Administrative Code § 704(i) and/or any other applicable provision of law;

c. That Relators be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiffs and Relators have such other and further relief that this Court deems just and proper.

COUNT THIRTY-THREE
City of Chicago False Claims Act
Municipal Code of Chicago §1-22-010-§1-22-060

1002. Plaintiffs incorporate by reference and re-allege all above paragraphs as if fully set forth herein.

1003. This is a claim for treble damages and penalties against all Defendant on behalf of the City of Chicago under the Chicago False Claims Act, Municipal Code of Chicago §1-22-010-§1-22-060.

1004. By virtue of the above-described acts, among others, Defendants knowingly and willfully promoted their drugs for non medically accepted uses.

1005. By virtue of the above-described acts, Defendants knowingly made or caused to be made false claims for Defendants drugs to the City of Chicago.

1006. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City of Chicago to approve and pay such false and fraudulent claims.

1007. The Chicago City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

1008. By reason of the Defendant's unlawful acts, the City of Chicago has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

COUNT THIRTY-FOUR
Montana False Claims Act
Mont. Code Ann. § 17-8-401 *et seq.*

1009. Plaintiffs Thorpe and Hamrick and the State of Montana reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1010. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Ann., § 17-8-401 *et seq.*

1011. The Montana False Claims Act, Mont. Code Ann., § 17-8-403 provides for liability for *inter alia* any person who engages in any or all of the following conduct.

(a) knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;
(b) knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;

(c) conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity; . . .

(h) as a beneficiary of an inadvertent submission of a false claim to the governmental entity, subsequently discovering the falsity of the claim and failing to disclose the false claim to the governmental entity within a reasonable time after discovery of the false claim.

1012. Defendant Defendants, acting in concert with its co-Defendants, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Montana.

1013. By virtue of the conduct alleged herein, including the exchange of kickbacks and submissions of non-reimbursable claims described above and the off-label marketing scheme described above, Defendants knowingly violated each of the above subsections of the Montana False Claims Act by and through their intentional and/or knowing violations of federal and state laws, including the Anti-Kickback Statute, as described herein.

1014. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of Defendants' illegal conduct, paid for claims that otherwise would not have been allowed.

1015. By reason of these improper payments, the Montana Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

1016. Thorpe and Hamrick are private persons with direct and independent knowledge of the allegations in this First Amended Complaint, who has brought this action pursuant to the Montana False Claims Act on behalf of themselves and the State of Montana.

1017. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

COUNT THIRTY-FIVE
Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-1-104 *et seq.*

1018. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

1019. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act.

1020. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

1021. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

1022. By virtue of the acts described above, defendants conspired with each other and with others to defraud Colorado by inducing the Colorado State Government to pay or approve false or fraudulent claims.

1023. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

1024. By reason of the defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1025. The State of Colorado is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT THIRTY-SIX
Minnesota False Claims Act
Minn. Stat. § 15C.01 *et seq.*

1026. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

1027. This is a claim for treble damages and penalties under the Minnesota False Claims Act.

1028. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

1029. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Minnesota State Government to approve and pay such false and fraudulent claims.

1030. By virtue of the acts described above, defendants conspired with each other and with others to defraud Minnesota by inducing the Minnesota State Government to pay or approve false or fraudulent claims.

1031. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

1032. By reason of the defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1033. The State of Minnesota is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants

COUNT THIRTY-SEVEN
Maryland False Health Claims Act of 2010
Subtitle 6, False Claims Against State Health Plans and
State Health Programs, § 2-601 *et seq.*

1034. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

1035. This is a claim for treble damages and penalties under the Maryland False Health Claims Act of 2010, Subtitle 6.

1036. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

1037. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

1038. By virtue of the acts described above, defendants conspired with each other and others to violate the Maryland False Health Claims Act of 2010.

1039. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

1040. By reason of the defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

1041. The State of Maryland is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT THIRTY-EIGHT
Iowa Medicaid False Claims Act, § 685.1 *et seq.*

1042. Plaintiffs restate and incorporate each and every allegation above as if the same were fully set forth herein.

1043. This is a claim for treble damages and penalties under the Iowa Medicaid False Claims Act.

1044. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to any employee, officer, or agent of Iowa, or to any contractor grantee or other recipient of Iowa funds for payment or approval.

1045. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, to get false claims paid or approved.

1046. By virtue of the acts described above, defendants conspired with each other and others to defraud Iowa by getting false claims allowed or paid.

1047. The Iowa State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

1048. By reason of the defendants' acts, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

1049. The State of Iowa is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants plus treble damages.

PRAYER FOR RELIEF

1. WHEREFORE, Plaintiffs pray for judgment that defendants cease and desist from violating 31 U.S.C. §3729 et seq., and the equivalent provisions of the state statutes set forth above;

2. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of California has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §12651(a);

4. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of the Connecticut False Claims Act, Chapter 319v, Sec. 17b-301 *et seq.*;

5. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

6. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of Fla. Stat. Ann. §68.082;

7. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

8. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

9. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

10. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

11. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained

because of defendants' actions, plus civil penalties for each violation of N.M. Stat. Ann. §27-14-1 et seq. and N.M. Stat. Ann. §44-9-1 et seq;

12. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendants' actions, plus a civil penalty for each violation of Tenn. Code Ann. §71-5-182(a);

13. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

14. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. §8.01-216.3(a);

15. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14(a);

16. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of O.C.G.A §§ 49-4-168 et seq;

17. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of defendants' actions, plus civil penalties for each violation of I.C. §5-11-5.5;

18. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437 et. seq.;

19. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of MCL 400.601 et seq.;

20. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of defendants' actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b(I);

21. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of New York has sustained because of defendants' actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. §§ 187 et seq.;

22. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 2007 OK. ALS 137;

23. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of defendants' actions, plus civil penalties for each violation of N.J. Stat. §2A:32C-1 et seq.;

24. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of defendants' actions, plus civil penalties for each violation of R.I. Gen. Laws §9-1.1-1 et seq.;

25. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages Wisconsin has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of the Wis. Stat. §20.931 et seq.;

26. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions plus a civil penalty of $11,000 for each violation of N.C. Gen. Stat. §§1-605 et seq.;

27. that this court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages Montana has sustained because of the defendants' actions, plus a civil penalty of $10,000 for each violation of the Montana False Claims Act, Mont. Code Ann., § 17-8-401 *et seq.*;

28. that by reason of the aforementioned violations of the New York City False Claims Act provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the

amount of damages that the City of New York has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $15,000 for each violation of the New York City False Claims Act, New York City Administrative Code §7-801-§7-810;

29. that by reason of the aforementioned violations of the Chicago False Claims Act provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the City of Chicago has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of the Municipal Code of Chicago §1-22-010-§1-22-060;

30. that this court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages Colorado has sustained because of the defendants' actions, plus a civil penalty of $10,000 for each violation of the Colorado Medicaid False Claims Act, Colo. Rev. Stat., § 25.5-1-104 *et seq.*;

31. that this court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages Minnesota has sustained because of the defendants' actions, plus a civil penalty of $11,000 for each violation of the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*;

32. that this court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages Maryland has sustained because of the defendants' actions, plus a civil penalty of $11,000 for each violation of the Maryland False Health Claims Act of 2010 (Subtitle 6, False Claims Against State Health Plans and State Health Programs, § 2-601 *et seq*.);

33. that this court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages Iowa has sustained because of the defendants' actions, plus a civil penalty of $10,000 for each violation of the Iowa Medicaid False Claims Act;

34. that Plaintiffs be awarded the maximum amount allowed pursuant to §3730(d) of the federal False Claims Act, and the equivalent provisions of the state statutes and statutes of the City of Chicago and New York City set forth above;

35. that Plaintiffs be awarded all costs of this action, including attorneys' fees and expenses; and,

36. that Plaintiffs recover such other relief as the Court deems just and proper, or that is necessary to make Plaintiffs whole.

Respectfully submitted this 30th day of January, 2012,

FOGELMAN & FOGELMAN LLC

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CERTIFICATE OF SERVICE

I hereby certify that on this 30TH day of January, 2012, I caused to be served and delivered via electronic mail a true and correct copy of the foregoing Plaintiffs' Seventh Amended Complaint upon the following:

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s/ Matthew J. Fogelman